DOCKET

SUPREME COURT
OF THE UNITED STATES

No. 09-1156
Title: Matrixx Initiatives, Inc., et al., Petitioners
v
James Siracusano, et al.
Docketed: March 24, 2010
Linked with 10A545
Lower Ct: United States Court of Appeals for the Ninth Circuit
Case Nos.: (06-15677)
Decision Date: October 28, 2009
Rehearing Denied: December 23, 2009
Questions Presented

---Date---	--------Proceedings and Orders----------
Mar 23 2010	Petition for a writ of certiorari filed. (Response due April 23, 2010)
Mar 31 2010	Waiver of right of respondents James Siracusano, et al. to respond filed.
Apr 7 2010	DISTRIBUTED for Conference of April 23, 2010.
Apr 14 2010	Response Requested. (Due May 14, 2010)
May 13 2010	Brief of respondents James Siracusano, and NECA-IBEW Pension Fund in opposition filed.
May 25 2010	DISTRIBUTED for Conference of June 10, 2010.
May 25 2010	Reply of petitioners Matrixx Initiatives, Inc., et al. filed. (Distributed)
Jun 14 2010	Petition GRANTED.
Jul 2 2010	The time within which to file the joint appendix and petitioners' brief on the merits is extended to and including August 13, 2010.
Jul 19 2010	The time within which to file the joint appendix and petitioners' brief on the merits is further extended to and including August 20, 2010.
Jul 28 2010	Consent to the filing of amicus briefs, in support of either party or of neither party, received from counsel for the respondents.
Jul 30 2010	Consent to the filing of amicus briefs, in support of either party or of neither party, received from counsel for the petitioner.
Aug 20 2010	Brief of petitioners Matrixx Initiatives, Inc., et al. filed.
Aug 20 2010	Joint appendix filed. (Statement of costs filed)
Aug 27 2010	Brief amici curiae of Consumer Healthcare Products Association and the Council for Responsible Nutrition filed.
Aug 27 2010	Brief amicus curiae of Natural Products Association filed.
Aug 27 2010	Brief amicus curiae of DRI - The Voice of the Defense Bar filed.
Aug 27 2010	Brief amicus curiae of BayBio filed.
Aug 27 2010	Brief amicus curiae of Product Liability Advisory Council, Inc. filed.
Aug 27 2010	Brief amicus curiae of Advanced Medical Technology Association filed.
Aug 27 2010	Brief amici curiae of Pharmaceutical Research and Manufacturers of America, et al. filed.
Aug 27 2010	Brief amici curiae of Securities Industry and Financial Markets Association, et al. filed.
Aug 27 2010	Brief amicus curiae of Washington Legal Foundation filed.
Sep 9 2010	The time within which to file the respondent's brief on the merits is extended to and including November 5, 2010.
Nov 5 2010	Brief of respondents James Siracusano, et al. filed. (Distributed)
Nov 8 2010	SET FOR ARGUMENT ON Monday, January 10, 2011.
Nov 12 2010	CIRCULATED.
Nov 12 2010	Brief amicus curiae of the United States filed. (Distributed)

Nov 12 2010	Motion of the Acting Solicitor General for leave to participate in oral argument as amicus curiae and for divided argument filed.
Nov 12 2010	Brief amici curiae of Economists Robert E. Litan and Joseph R. Mason filed. (Distributed)
Nov 12 2010	Brief amici curiae of Medical Researchers Dr. Tonia M. Young-Fadok, et al. filed. (Distributed)
Nov 12 2010	Brief amicus curiae of Professors at Law and Business Schools filed. (Distributed)
Nov 12 2010	Brief amici curiae of AARP and North American Securities Administrators Association, Inc., et al. filed. (Distributed)
Nov 12 2010	Brief amici curiae of Statistics Experts Professors Deidre N. McCloskey and Stephen T. Ziliak filed.
Nov 29 2010	Application (10A545) to extend the time to file a reply brief on the merits submitted to Justice Kennedy
Dec 2 2010	Application (10A545) granted by Justice Kennedy extending the time to file the reply brief on the merits until December 13, 2010.
Dec 2 2010	Record received from U.S.C.A. for 9th Circuit. (1 envelope)
Dec 6 2010	Motion of the Acting Solicitor General for leave to participate in oral argument as amicus curiae and for divided argument GRANTED.
Dec 13 2010	Reply of petitioners Matrixx Initiatives, Inc., et al. filed. (Distributed)
Dec 15 2010	Record received from U.S.D.C. for the District of Arizona (Phoenix). (1 box)
Jan 10 2011	Argued. For petitioners: Jonathan Hacker, Washington, D. C. For respondents: David C. Frederick, Washington, D. C., and Pratik A. Shah, Assistant to the Solicitor General, Department of Justice, Washington, D. C. (for United States, as amicus curiae.)

PETITION FOR WRIT OF CERTIORARI

Supreme Court, U.S.
FILED

091156 MAR 23 2010

No. 09- OFFICE OF THE CLERK

IN THE

Supreme Court of the United States

MATRIXX INITIATIVES INC., ET AL.,
Petitioners,

v.

JAMES SIRACUSANO AND NECA-IBEW PENSION FUND,
Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Respondents filed suit under § 10(b) of the Securities Exchange Act of 1934 and Securities and Exchange Commission Rule 10b-5, alleging that petitioners committed securities fraud by failing to disclose "adverse event" reports—i.e., reports by users of a drug that they experienced an adverse event after using the drug. The First, Second, and Third Circuits have held that drug companies have no duty to disclose adverse event reports until the reports provide statistically significant evidence that the adverse events may be caused by, and are not simply randomly associated with, a drug's use. Expressly disagreeing with those decisions, the Ninth Circuit below rejected a statistical significance standard and allowed the case to proceed despite the lack of any allegation that the undisclosed adverse event reports were statistically significant. The question presented is:

Whether a plaintiff can state a claim under § 10(b) of the Securities Exchange Act and SEC Rule 10b-5 based on a pharmaceutical company's nondisclosure of adverse event reports even though the reports are not alleged to be statistically significant.

PARTIES TO THE PROCEEDING

Petitioners are Matrixx Initiatives, Inc., Carl Johnson, William Hemelt, and Timothy Clarot, defendants-appellees below.

Respondents are James Siracusano, named plaintiff and appellant below, and the NECA-IBEW Pension Fund, lead plaintiff and appellant below, on behalf of themselves and all others similarly situated who purchased securities of Matrixx between October 22, 2003 and February 6, 2004.

RULE 29.6 DISCLOSURE

Matrixx Initiatives, Inc. has no parent corporation and no person or publicly-traded corporation owns more than 10% of Matrixx's stock.

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PETITION FOR A WRIT OF CERTIORARI

Petitioners respectfully seek a writ of certiorari to review the judgment of the United States Court of Appeals for the Ninth Circuit in this case.

OPINIONS BELOW

The decision of the court of appeals is reported at 585 F.3d 1167 and is reprinted in the Appendix to the Petition ("App.") at 1a-34a. The district court's opinion is available at 2005 WL 3970117 and is reprinted at App. 35a-54a.

JURISDICTION

The court of appeals issued its decision on October 28, 2009, and denied a petition for rehearing and rehearing *en banc* on December 23, 2009. App. 55a-56a. The Court's jurisdiction is invoked pursuant to 28 U.S.C. § 1254(1).

STATUTES AND REGULATION INVOLVED

The relevant statutory provisions of the Securities Exchange Act of 1934, 15 U.S.C. § 78j(b), and the Private Securities Litigation Reform Act of 1995 (PSLRA), 15 U.S.C. §§ 78u-4(b)(2), and Securities and Exchange Commission (SEC) Rule 10b-5 are reproduced in the appendix. App. 57a-58a.

INTRODUCTION

This case presents a question of recurring importance under § 10(b) of the Securities Exchange Act and SEC Rule 10b-5 on which the courts of appeals are squarely divided: whether drug companies have a duty to disclose "adverse event" reports—i.e., reports by users of a drug that they experienced an ad-

verse event after using the drug—where the reports do not reflect statistically significant evidence that the adverse event may be caused by use of the drug. Three Circuits have held that drug companies have no duty to disclose adverse event reports until the reports provide statistically significant evidence that the adverse events may be caused by, and are not simply randomly associated with, a drug's use. Expressly disagreeing with those decisions, the court below rejected a statistical significance standard and allowed the case to proceed based on the failure to disclose adverse event reports that are not statistically significant.

That decision has immense consequences for pharmaceutical companies, investors, and consumers. The Food and Drug Administration receives hundreds of thousands of adverse event reports each year. Those reports are made without regard to whether there is any established relationship between use of a drug and an adverse event. Under the court of appeals' ruling, a pharmaceutical company that fails to disclose a small number of such complaints would be subject to suit under § 10(b) even though the complaints are not statistically significant and therefore do not indicate any causal relationship between use of the drug and the adverse event.

Faced with that rule, the only safe course for a company would be to provide investors with every adverse event report even though the company has no reason to believe that the report casts the slightest doubt on the safety of the drug. That result is not only harmful to reasonable investors, who depend on receiving significant rather than useless in-

formation. It is also detrimental to consumers. If drug companies disclose every adverse event report, the unfortunate result may be to deter confused consumers from using drugs that would be beneficial to their health.

As three courts of appeals have correctly concluded, a statistical significance standard is necessary to prevent these untoward consequences. The Court should therefore grant certiorari to resolve the conflict in the circuits on this issue and hold that adverse event reports can form the basis for a claim under § 10(b) of the Securities Exchange Act and SEC Rule 10b-5 only when they are statistically significant.

STATEMENT OF THE CASE

1. Petitioner Matrixx Initiatives, Inc. is a pharmaceutical company that sells cold remedy products through its wholly-owned subsidiary, Zicam, LLC. App. 2a. One of Matrixx's main products is Zicam Cold Remedy (Zicam), which was produced in the form of a nasal spray or gel. Zicam's active ingredient is zinc gluconate. *See* App. 2a-3a, 4a.

On April 27, 2004, respondents brought suit on behalf of a putative class of investors who purchased Matrixx stock between October 22, 2003 and February 6, 2004. App. 4a. Respondents alleged that Matrixx and three of its executives (petitioners) violated § 10(b) of the Securities Exchange Act and SEC Rule 10b-5 by failing to disclose material information regarding Zicam Cold Remedy. Specifically, respondents alleged that use of Zicam could cause "anosmia," or loss of the sense of smell. App. 3a.

In support of their conclusory allegation of a causal connection between Zicam and anosmia, respondents relied on allegations that, in a four-year period between 1999 and 2004, Matrixx received approximately 12 reports of user anosmia: one from Dr. Alan Hirsch, another from Dr. Miriam Linschoten, and ten from Dr. Bruce Jafek. *See* App. 25a. Respondents also alleged that, in the class period, Matrixx was named in four Zicam-related lawsuits, involving a total of nine plaintiffs, and in their briefing, respondents counted those plaintiffs as additional complainants. App. 25a-26a. It is not clear whether those plaintiffs actually represent additional adverse events.[1] Ultimately, however, the precise number of adverse event reports is beside the point. The critical point, for present purposes, is that respondents did not allege in their complaint that the small number of adverse event reports in the class period was statistically significant, much less allege facts that would raise an inference of statistical significance.

2. Petitioners filed a motion to dismiss respondents' complaint for failure to state a claim. The district court granted the motion. App. 35a-54a. The court invoked the Second Circuit's decision in *In re Carter-Wallace, Inc. Securities Litigation*, 220 F.3d 36 (2d Cir. 2000), as the standard for determining when allegations of undisclosed adverse event reports can satisfy the materiality requirement under § 10(b) and Rule 10b-5. As the district court ex-

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[1] Respondents' complaint did not allege that the plaintiffs in the Zicam-related lawsuits were additional complainants, rather than simply a subset of the 12 individuals whose adverse events had already been reported to Matrixx.

plained, in *Carter-Wallace*, the Second Circuit held that no claim can be based on the nondisclosure of adverse event reports "unless such reports provide reliable statistically significant information that a drug is unsafe." App. 45a. Applying that standard, the district court concluded that respondents had alleged "no data as to the reliability and accuracy of the user complaints," and that "[e]ven if there were data as to the reliability" of the complaints, "12 user complaints is not statistically significant." App. 50a. The court therefore concluded that respondents failed to allege that the nondisclosure of the reports was a "material omission." *Id.*

The district court noted that the complaint alleged that by April 2004, after the class period had ended, there were 165 adverse event reports. App. 53a. It therefore allowed respondents to replead to cure the deficiency in the Complaint. But it warned that "[a]bsent allegations Defendants *knew* there was a definitive and statistically significant link between Zicam and anosmia *during the Class period* that was sufficiently serious and frequent to affect future earnings, any amendment would be futile." App. 54a (internal quotation marks omitted). The district court thereby used the statistical significance standard as a measure of both materiality and scienter.

3. The court of appeals reversed. The court recognized that "the [district] court relied on the statistical significance standard used by the Second Circuit in *In re Carter-Wallace, Inc. Securities Litigation*, 150 F.3d 153, 157 (2d Cir. 1999), and *In re Carter-Wallace, Inc. Securities Litigation*, 220 F.3d 36 (2d Cir. 2000)." App. 23a. The court of appeals

"conclude[d], however, that the district court erred in relying on the statistical significance standard" to rule on materiality. *Id.* According to the court, "reliance on the statistical significance standard is inconsistent with the Supreme Court's rejection of bright-line rules and its emphasis on having materiality determined by the trier of fact." App. 34a.

The court then held that the respondents "sufficiently pled materiality" based on the nondisclosure of the adverse event reports, even though the reports were not alleged to be statistically significant. App. 34a. And based on the number and nature of the reports, the court further held that the inference that petitioners withheld the reports "intentionally or with deliberate recklessness is at least as compelling as any plausible nonculpable explanation." *Id.*[2]

REASONS FOR GRANTING THE PETITION

THE COURT SHOULD GRANT REVIEW TO DECIDE WHETHER A PLAINTIFF CAN STATE A CLAIM UNDER § 10(B) AND RULE 10B-5 BASED ON NONDISCLOSURE OF ADVERSE EVENT REPORTS THAT ARE NOT STATISTICALLY SIGNFICANT

The courts of appeals are divided on whether a plaintiff can state a claim under § 10(b) of the Securities Exchange Act and SEC Rule 10b-5 based on a pharmaceutical company's failure to disclose adverse

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[2] While the appeal was pending in the Ninth Circuit, the FDA issued a warning letter, stating that some of the Zicam products "may pose a serious risk to consumers." App. 3a n.1. Because that warning letter was written more than five years after the close of the class period, it has no bearing on the question presented here.

event reports that are not statistically significant. That issue is an important and recurring one, not only for pharmaceutical companies and investors, but also for consumers who rely on the products those companies produce. This case presents an ideal vehicle for resolving that issue. And the court of appeals answered the question presented incorrectly. A plaintiff should be permitted to pursue a claim under § 10(b) based on nondisclosure of adverse event complaints only when those complaints are statistically significant. The Court should grant certiorari and reverse the judgment below.

A. The Courts of Appeals Are Divided on the Question Presented

The courts of appeals are divided on the question presented in this case. The First, Second, and Third Circuits have adopted a statistical significance standard for claims based on nondisclosure of adverse event reports, while the Ninth Circuit in this case expressly rejected a statistical significance standard.

1. a. *In re Carter-Wallace, Inc. Securities Litigation*, 150 F.3d 153 (2d Cir. 1998) (*Carter-Wallace I*), is the seminal decision adopting the statistical significance standard. In an opinion by Judge Winter, the Second Circuit held that a drug company's failure to disclose adverse event reports could "not be[] materially misleading until [the company] had information that [the drug] had caused a statistically significant number of" adverse events. *Id.* at 157. The court explained that "[d]rug companies need not disclose isolated reports of illnesses suffered by users of their drugs until those reports provide statistically significant evidence that the ill effects may be

caused by—rather than randomly associated with—use of the drugs." *Id.*

In *In re Carter-Wallace, Inc. Securities Litigation*, 220 F.3d 36 (2d Cir. 2000) (*Carter-Wallace II*), the Second Circuit reaffirmed that a claim under § 10(b) cannot be based on failure to disclose adverse event reports that are not statistically significant. In that case, the court of appeals explained that because adverse event reports to the FDA encompass any adverse event associated with a drug, "whether or not considered drug related," and because "[s]ome adverse events may be expected to occur randomly," such reports are not indicative of a "causal relationship" until they are "statistically significant." 220 F.3d at 41 (emphasis omitted). The court further held that nondisclosure of reports that are not statistically significant is not only "not materially misleading," but "any inference of scienter [is] negated as well." *Id.* Nor did it matter to the court that, after the class period ended, the drug was eventually linked to a series of deaths. The court explained that reports could not "relate back" in time and "reflect on Carter-Wallace's reasonable belief that the reports were random." *Id.* at 41. The Second Circuit continues to follow the statistical significance rule. *See Avon Pension Fund v. Glaxosmithkline PLC*, 343 F. App'x 671, 672-73 (2d Cir. 2009); *Masters v. Glaxosmithkline*, 271 F. App'x 46, 50 (2d Cir. 2008).

The Third Circuit has also adopted the statistical significance standard. In an opinion by then-Judge Alito, the Third Circuit held that "'drug companies need not disclose isolated reports of illnesses suffered by users of their drugs until those reports provide statistically significant evidence that the ill ef-

fects may be caused by—rather than randomly associated with—use of the drugs.'" *Oran v. Stafford*, 226 F.3d 275, 284 (3d Cir. 2000) (quoting *Carter-Wallace I*, 150 F.3d at 157). Because the reports at issue were not "statistically significant," the court held that their nondisclosure was not "materially misleading." *Id.*

Similarly, the First Circuit has adopted the statistical significance test. In *New Jersey Carpenters Pension & Annuity Funds v. Biogen IDEC Inc.*, 537 F.3d 35, 48 (1st Cir. 2008), the First Circuit rejected a plaintiff's § 10(b) claim that was based on nondisclosure of adverse event reports. The court explained that there was "no basis to conclude that these results . . . were statistically significant," and that "'the receipt of an adverse report does not in and of itself show a causal relationship between [a drug] and the illness mentioned in the report.'" *Id.* at 50, 53 (quoting *Carter-Wallace II*, 220 F.3d at 41) (emphasis omitted).

b. In conflict with the decisions of those three circuits, the court of appeals in this case squarely rejected "the statistical significance standard used by the Second Circuit in *In re Carter-Wallace*." App. 23a. The court explained that, in its view, "the district court's reliance on the statistical significance standard to conclude that [respondents] failed to establish materiality [was] inconsistent with the Supreme Court's rejection of bright-line rules and its emphasis on having materiality determined by the trier of fact." App. 34a.

2. As a result of the Ninth Circuit's rejection of the statistical significance standard, the pleading

requirements for stating a securities claim against a pharmaceutical company depend entirely on the jurisdiction in which a plaintiff chooses to bring suit. Companies defending suits in the First, Second, and Third Circuits will be able to obtain prompt dismissals of claims based on adverse event reports lacking statistical significance. Companies forced to defend securities fraud suits in the Ninth Circuit, however, will be required to proceed past the pleadings stage, with all the costs and pressure to settle unmeritorious suits that entails. That difference in treatment of similarly situated companies is intolerable.

The conflict in the circuits is particularly alarming given the class-action nature of most § 10(b) actions. Any plaintiff who can establish jurisdiction in a district court within the Ninth Circuit could prevent application of the statistical significance standard to a nationwide class of investors. In effect, the Ninth Circuit's rule gives any class action plaintiff who can secure jurisdiction within the Ninth Circuit's wide geographic region a ready weapon to blunt the protection against unmeritorious suits offered by the First, Second, and Third Circuits. This Court should grant certiorari to resolve the conflict in the circuits and prevent the Ninth Circuit's rule from effectively becoming the law of the land without review by this Court.

B. The Question Presented Is a Recurring Issue of National Importance, and This Case Presents an Ideal Vehicle for Resolving That Issue

1. The question presented is a frequently recurring issue of national importance, deserving of a uni-

form national resolution. In 2008 alone, the FDA received a total of 526,527 adverse event reports for drugs and therapeutic biologic products. *See* U.S. Food and Drug Administration, Adverse Event Reporting System (AERS), Reports Received and Reports Entered into AERS by Year (2010), http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm070434.htm. Under the court of appeals' approach, a small number of such reports, if undisclosed, could potentially form the basis for a lawsuit under § 10(b).

Plaintiffs are particularly likely to target the instances in which the FDA issues a warning letter or a recall. *See N.J. Carpenters*, 537 F.3d at 47. In fiscal year 2008, for example, the FDA's Center for Drug Evaluation and Research—the body responsible for regulating over-the-counter and prescription drugs—issued 379 product recalls and 87 warning letters. *See* U.S. Food and Drug Administration, *The Enforcement Story* 10-9, 10-16 (2009), http://www.fda.gov/downloads/ICECI/EnforcementActions/EnforcementStory/UCM129824.pdf. Under the court of appeals' standard, once such a letter or recall is issued, plaintiffs would have every incentive to sue based on nondisclosure of adverse event reports made at an earlier time, even if there were no statistically significant evidence of a causal link between the drug and the effect at that time. *See, e.g.*, *Carter-Wallace I*, 150 F.3d at 157 (no claim where adverse reports received before company acted were not statistically significant).

The effects of the Ninth Circuit's rejection of the statistical significance standard are profoundly un-

settling. The court's decision dramatically expands the number of investor suits against pharmaceutical companies that state a claim and substantially increases the pressure on companies to settle meritless claims.

The Court has previously granted review in similar circumstances. In *Dura Pharmaceuticals, Inc. v. Broudo*, the Court rejected a Ninth Circuit rule that "permit[ted] a plaintiff with a largely groundless claim to simply take up the time of a number of other people, with the right to do so representing an *in terrorem* increment of the settlement value, rather than a reasonably founded hope that the [discovery] process will reveal relevant evidence." 544 U.S. 336, 347 (2005) (internal quotation marks omitted); *see In re Rhone-Poulenc Rorer, Inc.*, 51 F.3d 1293, 1298 (7th Cir. 1995) (Posner, C.J.) (recognizing the "intense pressure to settle" if a class is certified). The court of appeals' decision in this case has the same effect, forcing defendants to undergo discovery and the risk of class certification for claims that have no basis in medical reality.

To avoid these intolerable effects, a company's only safe alternative would be to provide investors with every adverse event report even though it has no reason to believe that the report casts the slightest doubt on the safety of the drug and even though it has no material significance to a reasonable investor. As the Court has recognized before, providing investors with such information "is hardly conducive to informed decisionmaking." *TSC Indus., Inc. v. Northway, Inc.*, 426 U.S. 438, 448-49 (1976).

Disclosing every adverse event report would also be detrimental to consumers. Because such information, no matter how carefully phrased, is likely to spawn confusion, the unfortunate effect would be to deter consumers from purchasing drugs that are needed to improve their health.

The resolution of the question presented in this case is therefore of great importance to pharmaceutical companies, investors, and consumers. For that reason, review of that question is clearly warranted.

2. This case also presents an ideal vehicle for resolving the question presented. In a four-year period in which Matrixx made countless sales of Zicam, respondents were able to identify 12 adverse event reports. Respondents did not allege in their complaint that the reports were statistically significant, nor did they allege facts that would support a plausible inference of statistical significance.

Application of the statistical significance standard therefore would result in dismissal of the complaint. Indeed, applying the statistical significance standard, the district court did precisely that. And while the court of appeals reversed that dismissal, it did so only because it rejected the statistical significance standard. This case therefore squarely presents the question whether a plaintiff can state a § 10(b) claim based on nondisclosure of adverse event reports that are not statistically significant.

C. The Court of Appeals Erred in Rejecting the Statistical Significance Standard

1. The Ninth Circuit erred in rejecting the statistical significance standard adopted by the First, Sec-

ond, and Third Circuits. This Court held in *Basic* that information is not material under the securities laws unless there is "'a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available.'" *Basic Inc. v. Levinson*, 485 U.S. 224, 231-32 (1988) (quoting *TSC Indus.*, 426 U.S. at 449). "The role of the materiality requirement" is to "filter out essentially useless information that a reasonable investor would not consider significant." *Id.* It is not to bury investors in an "avalanche of trivial information." *TSC Indus.*, 426 U.S. at 448.

The statistical significance standard properly implements that materiality requirement. When adverse event reports are not statistically significant, they fail to provide any indication that the effects "may be caused by . . . use of the drugs." *Carter Wallace I*, 150 F.3d at 157. Instead, they indicate no more than a random relationship between use of the drug and the effect. *Id.* Accordingly, as the courts that have adopted the statistical significance standard have concluded, such reports are not material: they would not be viewed by reasonable investor as "significantly altering the 'total mix' of information made available." *Basic*, 485 U.S. at 231-32.

2. The Ninth Circuit rejected the statistical significance requirement because it believed that any "bright-line rule" for materiality is inconsistent with *Basic*. App. 34a But the Court in *Basic* rejected the bright-line rule proposed in that case because it was based on policy considerations that were not tied to "the significance of the information upon the investor's decision." 485 U.S. at 234. The statistical sig-

nificance standard, by contrast, is directly tied to the significance of adverse event reports to a reasonable investor. As noted above, the statistical significance standard captures the common sense insight that no reasonable investor would be likely to deem important reports of adverse events that are not statistically significant.

In *Jackvony v. RIHT Financial Corp.*, 873 F.2d 411, 415 (1st Cir. 1989), the First Circuit, in a post-*Basic* case, similarly adopted a bright-line rule that was directly tied to the importance of the information to a reasonable investor. In an opinion by then-Judge Breyer, the First Circuit held that internal discussion regarding a merger feeler from another company that precedes any merger negotiations is categorically non-material. The court explained that "[a]ny reasonably sophisticated investor in securities buying shares in a large corporation would expect that, from time to time, other corporations might express an interest in buying, or that the large corpo ration's directors might discuss what it should do if it obtains such offers." *Id.* The court added that "[f]or large corporations to make public announcements every time directors discuss any such matter in terms as vague as those presented in this evidence or receive 'tentative feelers' of the general sort revealed by th[e] evidence [before the court] . . . would more likely confuse, than inform, the marketplace." *Id.*

The same kind of analysis applies here. Any reasonably sophisticated investor buying shares in a pharmaceutical company must realize that consumers will, from time to time, experience adverse events after using the company's product. *Carter-*

Wallace II, 220 F.3d at 41. "Some adverse events may be expected to occur randomly, especially with a drug designed to treat people that are already ill." *Id.* Consequently, until adverse reports suggest "the ill effects may be caused by—rather than randomly associated with—use of the drug[]," no reasonable investor would likely deem that information material. *Carter-Wallace I*, 150 F.3d at 157. Requiring disclosure of every adverse report, as the court of appeals effectively did below, "would more likely confuse, than inform, the marketplace." *Jackvony*, 873 F.2d at 415. The court of appeals therefore erred in rejecting the statistical significance standard.

3. In addition, application of a statistical significance requirement is necessary to comport with the PSLRA's requirement that plaintiffs "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2). This Court in *Tellabs* held that, "[t]o qualify as 'strong' within the intendment of § 21D(b)(2) . . . an inference of scienter must be more than merely plausible or reasonable—it must be cogent and at least as compelling as any opposing inference of nonfraudulent intent." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 314 (2007).

Where adverse event reports are not statistically significant, the inference of fraudulent intent is not "at least as compelling as any opposing inference of nonfraudulent intent." *Id.* Instead, the more compelling inference is that defendants did not disclose information that was not statistically significant because it was medically meaningless. Thus, as the Second Circuit held in *Carter-Wallace II*, nondisclo-

sure of reports that are not statistically significant is not only "not materially misleading," but "any inference of scienter [is] negated as well." 220 F.3d at 41. For that reason as well, the court of appeals erred in rejecting the statistical significance standard. To resolve the conflict in the circuits on this issue of recurring importance and to correct the error by the court below, this Court's review is warranted.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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March 23, 2010

APPENDIX

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APPENDIX A

COURT OF APPEALS OPINION

FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

JAMES SIRACUSANO, Individually and on behalf of all others similarly situated,

Plaintiff-Appellant,

NECA-IBEW PENSION FUND,

Claimant-Appellant,

v.

MATRIXX INITIATIVES, INC.; Carl J. Johnson; William J. Hemelt,

Defendants-Appellees.

No. 06-15677

D.C. Nos.
CV 04-0886 MHM
CV 04-1012 MHM

OPINION

Appeal from the United States District Court
for the District of Arizona
Mary H. Murguia, District Judge, Presiding

Argued and Submitted
June 9, 2009—San Francisco, California

Filed October 28, 2009

Before: Mary M. Schroeder, A. Wallace Tashima and Carlos T. Bea, Circuit Judges.

Opinion by Judge Tashima

COUNSEL

Joseph D. Daley, Coughlin Stoia Geller Rudman & Robbins LLP, San Diego, California, for the plaintiff-appellant.

Michael G. Yoder, O'Melveny & Myers LLP, Newport Beach, California, for the defendants-appellees.

OPINION

TASHIMA, Circuit Judge:

Matrixx Initiatives, Inc. ("Matrixx") is a pharmaceutical company that sells cold products through its wholly-owned subsidiary, Zicam, LLC. One of its main products is Zicam Cold Remedy, which comes in several different forms.[1] Plaintiffs-

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[1] On June 16, 2009, the Food and Drug Administration

Appellants are lead plaintiff, NECA-IBEW Pension Fund, and named plaintiff, James Siracusano, in a class action brought against Matrixx and three Matrixx executives (collectively "Appellees") under the Private Securities Litigation Reform Act of 1995 ("PSLRA"). Appellants alleged that Appellees violated the Securities Exchange Act of 1934 by failing to disclose material information regarding Zicam Cold Remedy — specifically, that Zicam causes a condition called anosmia, which is a loss of the sense of smell, in its users. The district court granted in part and denied in part Appellees' motion to strike portions of the complaint and granted Appellees' motion to dismiss the complaint and the action. We have jurisdiction pursuant to 28 U.S.C. § 1291. We reverse and remand for further proceedings.

("FDA") issued a warning letter to Matrixx, setting forth the FDA's conclusion that several Zicam Cold Remedy products "may pose a serious risk to consumers who use them." http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm166909.htm (visited July 19, 2009; information moved to http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm166931.htm). The FDA stated that it had received "more than 130 reports of anosmia, (loss of sense of smell, which in some cases can be long-lasting or permanent), associated with use of these products." *Id.*

BACKGROUND[2]

On April 27, 2004, Appellants filed a class action against Matrixx and three individual defendants — Carl Johnson, Matrixx's Chief Executive Officer, President and a director; William Hemelt, Matrixx's Chief Financial Officer and Executive Vice President; and Timothy Clarot, Matrixx's Vice President and Director of Research and Development — on behalf of investors who purchased Matrixx securities during the class period, October 22, 2003, to February 6, 2004. Zicam Cold Remedy accounted for approximately 70 percent of Zicam's sales during the class period. Zicam Cold Remedy's active ingredient is zinc gluconate and can be applied as a nasal spray or a gel. Appellants alleged that Appellees were aware that numerous users of Zicam had developed anosmia, but that they failed to disclose the risk and instead issued false and misleading statements regarding Zicam.

I. Allegations of Adverse Information Regarding Zicam

In December 1999, Dr. Alan Hirsch, the Neurological Director of the Smell & Taste Treatment and Research Foundation, Ltd., "called Matrixx's customer service line to inquire into the

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[2] The following allegations are taken from the Consolidated Amended Complaint ("CAC"). In reviewing the district court's dismissal for failure to state a claim, we accept the plaintiffs' allegations as true and construe them in the light most favorable to the plaintiffs. *Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 989 (9th Cir. 2009). As such, the allegations are hereafter stated as fact.

amount of zinc contained in Zicam nasal gel." CAC ¶ 25. Hirsch spoke with a Mr. Landau and explained that at least one of Hirsch's patients had developed anosmia after using Zicam. Hirsch stated that other studies had indicated potential problems with "intranasal application of zinc," and offered to conduct a clinical study on the issue. Mr. Landau declined his offer.

In September 2002, Clarot, Vice President of Research and Development, called Miriam Linschoten, Ph.D., of the University of Colorado Health Sciences Center. Clarot contacted Linschoten because a patient Linschoten had treated for loss of smell following use of Zicam also had complained to Matrixx. Linschoten expressed concern that Zicam, an over-the-counter product, contained no warning that it could cause a loss of smell. Clarot told Linschoten that Matrixx had received similar complaints from other customers as early as 1999. Linschoten asked whether Matrixx had performed any studies, told Clarot about existing studies linking zinc sulfate to the loss of smell, and offered to send Clarot information regarding those studies. Clarot replied that Matrixx had not done any studies but that "it had hired a consultant to review the product." CAC ¶ 26.

On September 20, 2002, Linschoten sent an email to Clarot including abstracts on the link between zinc sulfate and the loss of smell. Clarot called Linschoten to ask if she would participate in animal studies to be conducted by Matrixx, but Linschoten declined because she focused on human, not animal, research.

Linschoten, Dr. Bruce Jafek of the University of

Colorado School of Medicine, and another colleague planned to submit their findings regarding ten patients who had developed anosmia following Zicam use in a presentation to the American Rhinologic Society on September 20, 2003. On September 12, 2003, "Matrixx sent a letter to Jafek stating that he did not have permission to use Matrixx's name or the names of its products" in the presentation. CAC ¶ 29. Jafek asked for permission to use the Zicam name, but Matrixx refused. The presentation to the American Rhinologic Society accordingly was made without naming Zicam. "Jafek's findings regarding Zicam were ultimately disclosed to the public on February 6, 2004 on *Good Morning America*." *Id.*

"As of April of 2004, Dr. Jafek had evaluated over 100 cases of anosmia following Zicam use." CAC ¶ 30. Linschoten had treated approximately 65 such patients, all of whom complained of "an 'immediate, severe burning' immediately following use of Zicam nasal gel, followed by a loss of smell." None of the patients had fully recovered. *Id.* Jafek and Hirsch "have observed that the Zicam nasal spray does reach the upper area of the nasal cavity where smell reception occurs."

II. Allegations of Misleading Statements

On October 22, 2003, Matrixx issued a press release announcing that its net sales for the third quarter of 2003 had increased by 163% over the third quarter of 2002. Johnson was quoted in the press release as follows:

> The Zicam brand is poised for growth in the upcoming cough and cold season with improved retail exposure by virtue of three [new] unique oral delivery forms of our Zicam

> Cold Remedy product, the resumption of our television advertising campaigns in recent weeks and the momentum from last year's successful season. Additionally, our retail partners have come to rely on the Zicam brand not only as an efficacious product for their customers, but also for the profitability that Zicam branded products produce for their respective bottom-lines.

Matrixx 10/22/2003 press release. Appellants alleged that these statements were materially false and misleading because they failed to disclose Appellees' awareness of the material health risk that Zicam posed to consumers.

On October 23, 2003, Appellees held an earnings conference call, at which Johnson expressed his "enthusiasm for the most recently completed quarter" and his "optimis[m] about the future." 10/23/03 Tr. at 1. Johnson explained that

> we have very strong momentum going into the upcoming cough and cold season. In addition, what lies behind these results is a unique product in the Zicam product line, a product that offers a unique benefit, the ability for consumers to actually reduce the duration and severity of the common cold, not just mask the symptoms, and tremendous support that we are receiving from our retail customers.

Id. at 2. Johnson further expressed the expectation for the year that "our revenues will be up in excess of 50% and that earnings per share for the full year will be in the 25-30¢ range." Id. at 5. Hemelt stated that the growth "was driven by increased sales of all

10 of our Zicam products," explaining that approximately one-third of the increase in sales was due to "three new Zicam oral cold remedy products," and that the remainder of the increase "was due to increased sales of our other seven Zicam products." *Id.* at 4. Johnson and Hemelt then answered questions.

At one point, they were asked to "make any comment on the litigation MTXX or its officers are involved in, or whether or not there is any SEC [Securities and Exchange Commission] investigation." *Id.* at 17. They replied that "[t]he officers of this company are not involved in any litigation," and that they were not aware of any SEC investigation.[3] *Id.* at 17-18. Johnson concluded by reiterating "the optimism we have for the future." *Id.* at 32. There was no mention of the anosmia issue.

On November 12, 2003, Matrixx filed its Form 10-Q report for the third quarter of 2003 with the SEC. The section of the Form 10-Q that Appellants alleged was false and misleading was this paragraph from the section on Risk Factors:

> *We may incur significant costs resulting from product liability claims*
>
> We are subject to significant liability should

---

[3] A lawsuit was filed against Matrixx and Zicam on October 14, 2003, in the United States District Court for the Western District of Michigan, alleging that Zicam caused anosmia. Matrixx was served on October 23, 2003, the day of the earnings conference call. *Christensen v. Matrixx Initiatives, Inc.*, No. 03-cv-0146, Docket No. 3.

> use or consumption of our products cause injury, illness or death. Although we carry product liability insurance, there can be no assurance that our insurance will be adequate to protect us against product liability claims or that insurance coverage will continue to be available on reasonable terms. A product liability claim, even one without merit or for which we have substantial coverage, could result in significant legal defense costs, thereby increasing our expenses and lowering our earnings. Such a claim, whether or not proven to be valid, could have a material adverse effect on our product branding and goodwill, resulting in reduced market acceptance of our products. This in turn could materially adversely affect our results of operations and financial condition.

CAC ¶ 35. Appellants alleged that these statements were materially false and misleading because Appellees "failed to disclose that a lawsuit alleging that Zicam caused anosmia had already been filed and, given the findings of the researchers at the University of Colorado it was highly likely that additional suits would be filed in the future." *Id.*

Matrixx issued a press release on January 7, 2004, in which it "upwardly revised its guidance for fiscal year 2003. The Company expects total 2003 revenues to grow by greater than 80 percent compared to 2002 and fully diluted earnings per share to be in the range of $0.33 to $0.38." CAC ¶ 37. Matrixx reported that "[t]he increase in the guidance for 2003 reflects a much greater incidence of colds than previously anticipated." *Id.*

On January 30, 2004, an article in the Dow Jones Newswires reported that the FDA was "looking into complaints that an over-the-counter common-cold medicine manufactured by a unit of Matrixx Initiatives Inc. (MTXX) may be causing some users to lose their sense of smell." The article stated that "[t]he FDA's interest follows at least three lawsuits filed by individuals against Matrixx and Zicam LLC, a wholly-owned subsidiary, by users of Zicam Cold Remedy." Appellants alleged that Matrixx's stock declined after this report, "falling from $13.55 per share on January 30, 2004 to $11.97 per share on February 2, 2004." CAC ¶ 41.

On February 2, 2004, Matrixx issued a press release, "respond[ing] to the Dow Jones 'In The Money report: FDA Looks Into Complaints About Zicam,' by Carol S. Remond, alleging that the FDA is investigating consumer complaints regarding intranasal zinc gluconate-induced loss of smell." Matrixx 2/2/2004 press release. The press release stated:

> Matrixx Initiatives, Inc., the manufacturer of Zicam(R) Cold Remedy, is not aware of an FDA inquiry into the safety of our intranasal zincgluconate products . . . .
>
> All Zicam products are manufactured and marketed according to FDA guidelines for homeopathic medicine. Our primary concern is the health and safety of our customers and the distribution of factual information about our products. Matrixx believes statements alleging that intranasal Zicam products cause anosmia (loss of smell) are completely unfounded and misleading.

In no clinical trial of intranasal zinc gluconate gel products has there been a single report of lost or diminished olfactory function (sense of smell). Rather, the safety and efficacy of zinc gluconate for the treatment of symptoms related to the common cold have been well established in two double-blind, placebo-controlled, randomized clinical trials. In fact, in neither study were there any reports of anosmia related to the use of this compound. The overall incidence of adverse events associated with zinc gluconate was extremely low, with no statistically significant difference between the adverse event rates for the treated and placebo subsets. A multitude of environmental and biologic influences are known to affect the sense of smell. Chief among them is the common cold. As a result, the population most likely to use cold remedy products is already at increased risk of developing anosmia. Other common causes of olfactory dysfunction include age, nasal and sinus infections, head trauma, anatomical obstructions, and environmental irritants.

The circumstances surrounding the development of Ms. Remond's column are extremely suspect. The article appeared online in public financial message boards almost immediately following its availability through the Dow Jones 'In The Money' subscription-only service. At least one of these message board postings was made by a registered user-name frequently used by Floyd Schneider, a defendant currently being

sued for defamation by Matrixx Initiatives. From at least August 2001 to the present, Schneider has posted false and defamatory statements about Matrixx on various Internet message boards using a variety of anonymous aliases. It has come to our attention that Schneider has also attempted to interfere with Matrixx' business by contacting our retail customers.

Ms. Remond's article appears on today's Dow Jones Newswire – the very day that Matrixx Initiatives is deposing Schneider. We believe that the timing of this article was manipulated by Schneider to interrupt the deposition process. We know that Ms. Remond and Schneider were in close communication during the development of Ms. Remond's article and even discussed the disclosure statement detailing the basis for our suit against Schneider, which has not yet been made public. Therefore, it is particularly troubling that Ms. Remond neglected to mention the defamation action or that Schneider was one of her chief sources of information. We consider her failure to mention these facts to be a significant omission in fair and balanced reporting.

Matrixx Initiatives would like to underscore that we intend to vigorously pursue those individuals involved in any effort to improperly discredit the company and its products. Furthermore, we strongly urge Dow Jones to open its own investigation to determine whether Dow Jones' credibility was undermined by the use of copyrighted

> material in an attempt to do further harm to the value and reputation of Matrixx Initiatives and its products.

Matrixx 2/2/2004 press release. Appellants alleged that Matrixx's "vigorous, but baseless, denials had their intended effect: the stock price rose, closing at $13.40 per share on February 3, 2004." CAC ¶ 41.

On February 6, 2004, the television show *Good Morning America* did a report on Matrixx's zinc gluconate products and anosmia. Reporter John Ferrugia reported that Jafek had treated "'more than a dozen patients'" and that four lawsuits had been filed, and others were "'being prepared.'" CAC ¶ 42. Appellants alleged that, "[i]n response to the *Good Morning America* segment . . . , the price of Matrixx common stock plummeted, falling from $13.05 per share on February 5, 2004, to close at $9.94 per share on February 6 — a one-day drop of 23.8% on unusually heavy trading volume." CAC ¶ 3.

On February 6, 2004, Matrixx issued another press release, describing the reports linking anosmia with zinc gluconate intranasal gels as "completely unfounded and misleading." Matrixx 2/6/2004 press release. Matrixx "assure[d] our consumers that Zicam Cold Remedy / intranasal zinc gluconate products are manufactured and marketed according to Food and Drug Administration guidelines for homeopathic medicine." *Id.* Matrixx further asserted as follows:

> In no clinical trial of intranasal zinc gluconate gel products has there been a single report of lost or diminished olfactory function (sense of smell). Rather, the safety and

> efficacy of zinc gluconate for the treatment of symptoms related to the common cold have been well established in two double-blind, placebo-controlled, randomized clinical trials. In fact, in neither study were there any reports of anosmia related to the use of this compound. The overall incidence of adverse events associated with zinc gluconate was extremely low, with no statistically significant difference between the adverse event rates for the treated and placebo subsets.
>
> A multitude of environmental and biologic influences are known to affect the sense of smell. Chief among them is the common cold. As a result, the population most likely to use cold remedy products is already at increased risk of developing anosmia. . . .
>
> A few researchers have attempted to link nasal products containing zinc to the onset of anosmia. However, this hypothesis is based on data from polio studies conducted in the 1930s using a concentrated zinc sulfate solution. Current nasal products, such as Zicam Cold Remedy, contain zinc gluconate, which is an entirely different compound.

Matrixx 2/6/2004 press release.

On February 19, 2004, Appellees filed a Form 8-K with the SEC, in which Matrixx stated that it had "convened a two-day meeting of physicians and scientists to review current information on smell disorders." CAC ¶ 45. The form stated that the meeting was in response to the September 20, 2003, presentation to the American Rhinologic Society.

The form further stated that, "[i]n the opinion of the panel, there is insufficient scientific evidence at this time to determine if zinc gluconate, when used as recommended, affects a person's ability to smell."

On March 4, 2004, Ferrugia, the reporter on the *Good Morning America* segment, reported on TheDenverChannel.com that Matrixx "now admit[ted] that they don't know if their nasal gel could cause loss of smell." CAC ¶ 47. The article stated that "[t]he stunning information came after a 7NEWS investigation found that some consumers who have used Zicam report the loss of smell." *Id.* The article reported that Matrixx initially "told us its studies showed the product [was] safe," but that it would begin studies to determine if the product could cause the loss of smell. *Id.* (alteration in original). The article further provided as follows:

> have filed complaints with the Food and Drug Administration. In response, the company formed a medical advisory panel in February. It says it will now conduct: ". . . animal and human studies to further characterize these post-marketing complaints." Study findings are expected to be available in 12 months. "It seems to me that those studies should have been done before they put the product on the market," said Jafek.

Id.

On March 19, 2004, Matrixx filed its Form 10-K with the SEC, stating that "numerous suits alleging that its Zicam product(s) caused anosmia had been filed." CAC ¶ 48. "As of December 31, 2003, suits involving three users of the Zicam® Cold Remedy nasal gel products had been filed in various federal and state courts." *Id.* Appellants stated that, "[a]ccording to Matrixx's own SEC filings, from late 2003 through October 2004 Matrixx has been sued by approximately 284 individuals in 19 different lawsuits alleging that Zicam caused damage to their sense of smell," and included in the complaint a table detailing the lawsuits. CAC ¶ 49. The table included suits filed on October 14, 2003, December 8, 2003, December 18, 2003, and January 23, 2004, as well as numerous suits following the close of the class period.

Appellants alleged that the financial information contained in Matrixx's Form 10-Q filed on November 12, 2003, was false and misleading and violated SEC rules and the Generally Accepted Accounting Principles ("GAAP") promulgated by the Financial Accounting Standards Board ("FASB"). Appellants

asserted that, at the time Matrixx filed the Form 10-Q,

> Matrixx should have disclosed, if not provided a reserve for, a potential contingency that had arisen related to safety issues concerning its products. During the Class Period, Matrixx did not disclose that several lawsuits had been filed against the Company, including one prior to the start of the Class Period, alleging that the Company's zinc gluconate-based products had caused plaintiffs to suffer from anosmia and that anecdotal evidence had surfaced questioning the safety of the Company's mainstay cold medication. The failure to disclose these known contingencies violated GAAP.

CAC ¶ 55. Appellants listed the FASB rules violated by Matrixx's Form 10-Q and asserted that "the undisclosed adverse information concealed by defendants during the Class Period is the type of information which, because of SEC regulations, . . . is expected by investors . . . to be disclosed and is known by corporate officials . . . to be the type of information which is expected to be and must be disclosed." CAC ¶¶ 56-57.

Appellants alleged that, "[a]s a result of defendants' materially false and misleading statements and failure to disclose adverse information regarding Zicam, Matrixx securities traded at artificially inflated prices during the Class Period." CAC ¶ 58. Appellants also alleged that, "[d]uring the Class Period, defendants materially misled the investing public, thereby inflating the price of Matrixx common stock, by publicly issuing

false and misleading statements and omitting to disclose material adverse facts regarding Zicam, necessary to make defendants' statements, as set forth herein not false and misleading." CAC ¶ 59.

In the section of the complaint entitled "Additional Scienter Allegations," Appellants alleged as follows:

> [D]efendants acted with scienter in that defendants knew that the public statements or documents issued or disseminated in the name of the Company were materially false and misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws. As set forth elsewhere herein in detail, defendants, by virtue of their receipt of information reflecting the true facts regarding Matrixx, their control over, and/or receipt and/or modification of the Company's alleged materially misleading misstatements and/or their associations with the Company which made them privy to confidential proprietary information concerning Matrixx, participated in the fraudulent scheme alleged herein.
>
> Defendants were aware since at least September of 2003, that numerous users of their Zicam product had experienced a rare condition known as anosmia or loss of smell. Findings of post treatment anosmia were

> reported by Dr. Bruce Jafek, Miriam R. Linschoten and Bruce W. Morrow of the University of Colorado School of Medicine, Department of Otolaryngology at a medical conference in September of 2003. At the time, Dr. Jafek had reported 10 cases of anosmia after Zicam use. As of April of 2004, Dr. Jafek had evaluated over 100 such cases. On September 12, 2003, over one month before the start of the Class Period, Matrixx informed Dr. Jafek that "as a legal matter" he did "not have their permission to use their company name or product trademarks" in the poster reporting Dr. Jafek's research. In order to avoid threatened legal action from the Company, Dr. Jafek deleted any reference to Zicam or Matrixx from the poster which he used to present his research at a medical conference.[4]

CAC ¶¶ 63-64.

Appellees filed a motion to strike any allegations that concerned user complaints and lawsuits that occurred after the close of the class period. The district court denied the motion in part and granted it in part. The court reasoned that the relevant inquiry was not whether there was a link between Zicam and anosmia, but whether Appellees knew that their statements were false at the time they were made. The court therefore denied the motion to

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[4] We do not disturb the district court's order granting, in part, Appellees' motion to strike portions of the CAC related to research published after the close of the class period.

strike as to the complaints and lawsuits that were filed because those allegations were relevant to Appellees' knowledge of user complaints. However, the court granted the motion to strike as to Jafek's ultimate conclusions, which were published after the close of the class period.

The district court then dismissed the complaint without prejudice, reasoning, that the allegations of user complaints were not material because they were not statistically significant. The court also found that Appellants had failed sufficiently to allege scienter.

The court further stated that any amendment would be futile "[a]bsent allegations Defendants *knew* there was a definitive and statistically significant link between Zicam and anosmia *during the Class Period* that was 'sufficiently serious and frequent to affect future earnings.'" The court therefore granted the motion to dismiss and dismissed the complaint without prejudice. The court then entered judgment, dismissing the complaint and the action without prejudice.[5] Appellants timely appealed.

STANDARD OF REVIEW

The district court's dismissal for failure to state a

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[5] Although the judgment dismisses the action without prejudice, it is "final for purposes of [28 U.S.C.] § 1291 [because] it (1) is a full adjudication of the issues, and (2) clearly evidences the judge's intention that it be the court's final act in the matter." *Elliott v. White Mountain Apache Tribal Court*, 566 F.3d 845, 846 (9th Cir. 2009).

claim is reviewed de novo. *Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 989 (9th Cir. 2009). We accept the plaintiffs' allegations as true and construe them in the light most favorable to the plaintiffs. *Id.* Dismissal is "inappropriate unless the plaintiffs' complaint fails to 'state a claim to relief that is plausible on its face.'" *Id.* (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)).

DISCUSSION

"Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), in combination with SEC Rule 10b-5, prohibits 'any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person, in connection with the purchase or sale of any security.'" *Rubke v. Capitol Bancorp Ltd.*, 551 F.3d 1156, 1164 (9th Cir. 2009) (quoting 17 C.F.R. § 240.10b-5(c)). In order adequately to allege a violation of Rule 10b-5, "a plaintiff must [allege] '(1) a material misrepresentation or omission of fact, (2) scienter, (3) a connection with the purchase or sale of a security, (4) transaction and loss causation, and (5) economic loss.'" *Id.* (quoting *In re Daou Sys., Inc.*, 411 F.3d 1006, 1014 (9th Cir. 2005)). The district court dismissed the complaint on the grounds that Appellants failed adequately to allege the first two elements; therefore, we address only those two elements.

I. Materiality

Appellants contend that Appellees' failure to disclose information regarding the possible link between Zicam and anosmia constituted the omission of a material fact. "An omitted fact is material if there is a substantial likelihood that a reasonable shareholder would consider it important

in deciding how to vote." *TSC Indus., Inc. v. Northway, Inc.*, 426 U.S. 438, 449 (1976).

"'Questions of materiality . . . involv[e] assessments peculiarly within the province of the trier of fact.'" *SEC v. Talbot*, 530 F.3d 1085, 1097 (9th Cir. 2008) (quoting *Arrington v. Merrill Lynch, Pierce, Fenner & Smith, Inc.*, 651 F.2d 615, 619 (9th Cir. 1981)) (alterations in original). Thus, "the ultimate issue of materiality [is] appropriately resolved 'as a matter of law'" only where the omissions are "'so obviously important to an investor, that reasonable minds cannot differ on the question of materiality.'" *TSC*, 426 U.S. at 450 (quoting *Johns Hopkins Univ. v. Hutton*, 422 F.2d 1124, 1129 (4th Cir. 1970)).

The district court summarized the "allegations of links between Zicam and anosmia for which Defendants had knowledge" as follows: "a phone conversation between a Matrixx vice-president and University of Colorado researcher discussing one anosmia complaint, a 1999 study recognizing a possible link, and a University of Colorado study citing 11 cases of anosmia in Zicam users."[6] District

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[6] The district court also reasoned that "Matrixx conducted a double-blind study regarding Zicam and not a single case of anosmia was reported." This was presumably a reference to Matrixx's February 2, 2004, press release, which states that "the safety and efficacy of zinc gluconate for the treatment of symptoms related to the common cold have been well established in two double-blind, placebo-controlled, randomized clinical trials." The press release, however, does not state that any tests established that the application of zinc gluconate to the nose is safe. In fact, as reported by Ferrugia on March 4,

Ct. Order at 11. The court then found that Appellants had failed adequately to allege materiality because the number of complaints of which Appellees were aware was not "statistically significant." The court relied on the statistical significance standard used by the Second Circuit in *In re Carter-Wallace, Inc. Securities Litigation*, 150 F.3d 153, 157 (2d Cir. 1998), and *In re Carter-Wallace, Inc. Securities Litigation*, 220 F.3d 36 (2d Cir. 2000). We conclude, however, that the district court erred in relying on the statistical significance standard to conclude that Appellants failed adequately to allege materiality.

The Supreme Court has rejected the adoption of a bright-line rule to determine materiality because "'[t]he determination [of materiality] requires delicate assessments of the inferences a "reasonable shareholder" would draw from a given set of facts and the significance of those inferences to him.'" *Basic Inc. v. Levinson*, 485 U.S. 224, 236 (1988) (quoting TSC, 426 U.S. at 450) (second alteration in original). Instead, courts should engage in a "fact-specific inquiry" in assessing materiality. *Id.* at 240. Thus, "[d]etermining materiality in securities fraud cases 'should ordinarily be left to the trier of fact.'" *SEC v. Phan*, 500 F.3d 895, (9th Cir. 2007) (quoting

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2004, Matrixx allegedly subsequently admitted that "'they don't know if their nasal gel could cause loss of smell,'" and that they would "begin . . . testing to determine whether its zinc compound could be harmful when sprayed in the nose." Moreover, the complaint alleged that Clarot told Linschoten in September 2002 that Matrixx had not conducted any studies and asked her to participate in studies.

In re Apple Computer Sec. Litig., 886 F.2d 1109, 1113 (9th Cir. 1989)); *see also No. 84 Employer-Teamster Joint Council Pension Trust Fund v. Am. W. Holding Corp.*, 320 F.3d 920, 934-35 (9th Cir. 2003) (declining to adopt a bright-line rule to determine materiality, engaging in the fact-specific inquiry required by *Basic*, and finding that the plaintiffs had sufficiently pleaded materiality).

In relying on the statistical significance standard to determine materiality, the district court made a decision that should have been left to the trier of fact. Instead, we agree with the approach of the court in *In re Pfizer Inc. Securities Litigation*, 584 F. Supp. 2d 621 (S.D.N.Y. 2008), where the United States District Court for the Southern District of New York rejected the defendant pharmaceutical company's argument that the plaintiffs failed to plead materiality, which was based on the contention that three studies revealing adverse effects of the company's drug were not statistically significant. The court reasoned that it "cannot determine as a matter of law whether such links were statistically insignificant because statistical significance is a question of fact." *Id.* at 635-36.

Thus, we are to engage in the fact-specific inquiry required by *Basic*. In doing so, we must take the allegations in the complaint as true and construe them in the light most favorable to Appellants and determine whether the complaint "fails to state a claim to relief that is plausible on its face." *Zucco*, 552 F.3d at 989 (internal quotation marks omitted). The following allegations in the CAC go to the question of whether the information regarding the possible link between Zicam and anosmia was information that a reasonable investor would have

considered significant:

- In December 1999, Hirsch called Matrixx's customer service line and reported one patient who had developed anosmia after Zicam use and mentioned studies regarding intranasal application of zinc.
- In September 2002, Clarot called Linschoten because one of her patients had complained to Matrixx about Zicam and anosmia. Clarot told Linschoten that Matrixx had received similar complaints from other customers since 1999, and Linschoten told Clarot about studies linking zinc sulfate to loss of smell.
- On September 20, 2002, Linschoten sent Clarot an email with abstracts on the link between zinc sulfate and the loss of smell.
- In September 2003, Jafek presented findings about ten or eleven patients who suffered anosmia following Zicam use. Matrixx, through Clarot, stopped Jafek from using Matrixx's and Zicam's names in the presentation.
- On October 14, 2003, two plaintiffs filed suit against Matrixx in the United States District Court for the Western District of Michigan, alleging that Zicam caused anosmia.
- On December 8, 2003, a plaintiff filed suit against Matrixx in Los Angeles Superior Court regarding Zicam and anosmia.
- On December 18, 2003, another suit regarding Zicam and anosmia was filed against Matrixx in Alabama state court and removed to federal court.

- On January 23, 2004, five plaintiffs filed a consolidated suit against Matrixx in the Superior Court of Maricopa County, Arizona regarding Zicam and anosmia. An additional 261 plaintiffs later joined this action, after the close of the class period.

- By April 2004, Jafek "had evaluated over 100 cases of anosmia following Zicam use," and Linschoten had seen 65 cases, although the time period of these allegations is not clear.

We believe that the foregoing allegations are sufficient to meet the pleading requirement under the PSLRA, which requires that:

> the complaint shall specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information or belief, the complaint shall state with particularity all facts on which that belief is formed.

15 U.S.C. § 78u-4(b)(1). The allegations in the CAC are sufficient to meet that standard and, as well, to "nudge[ ] [Appellants'] claims across the line from conceivable to plausible." *Twombly*, 550 U.S. at 570. Appellants have sufficiently alleged materiality, and the district court's finding to the contrary is reversed.

II. Scienter

In order to plead scienter, the PSLRA requires the complaint to "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2). The plaintiff "must allege that . . . the

defendant had an intention 'to deceive, manipulate, or defraud.'" *Metzler Inv. GMBH v. Corinthian Colls., Inc.*, 540 F.3d 1049, 1065-66 (9th Cir. 2008) (quoting *Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 193 (1976)). "[I]n determining whether the pleaded facts give rise to a 'strong' inference of scienter, the court must take into account plausible opposing inferences." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 310 (2007). The complaint will survive a motion to dismiss "only if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *Id.* at 324. This does not mean that a plaintiff must "plead more than she would be required to prove at trial." *Id.* at 311. Rather, "[a] plaintiff alleging fraud under § 10(b) action . . . must plead facts rendering an inference of scienter at least as *likely* as any plausible opposing inference." *Id.*

To establish scienter, "a complaint must 'allege that the defendants made false or misleading statements either intentionally or with deliberate recklessness.'" *Zucco*, 552 F.3d at 991 (quoting *Daou*, 411 F.3d at 1015). We must first "determine whether any of the plaintiff 's allegations, standing alone, are sufficient to create a strong inference of scienter." *Id.* at 992. If not, we are to "conduct a 'holistic' review of the same allegations to determine whether the insufficient allegations combine to create a strong inference of intentional conduct or deliberate recklessness." *Id.* Recklessness is defined as

> a highly unreasonable omission, involving not merely simple, or even inexcusable negligence, but an extreme departure from the standards of ordinary care, and which

> presents a danger of misleading buyers or sellers that is either known to the defendant or is so obvious that the actor must have been aware of it.

In re Silicon Graphics Inc. Sec. Litig., 183 F.3d 970, 976 (9th Cir. 1999) (quoting *Hollinger v. Titan Capital Corp.*, 914 F.2d 1564, 1569 (9th Cir. 1990) (en banc)).

The district court here concluded that the CAC failed to allege the requisite scienter because it "fails to allege any motive or state of mind with relation to the alleged omissions." In order adequately to allege scienter, Appellants rely on their allegations that Appellees knew about the problems with Zicam but chose not to reveal them. Appellants also argue that the importance of Zicam to Matrixx's business supports the inference that Appellees intentionally withheld information of the link between Zicam and anosmia. Appellants also point to the revelations following the close of the class period that, contrary to their statements during the class period, Matrixx actually did not know if Zicam caused anosmia and decided to conduct studies after they had already vouched for the safety of Zicam.

Matrixx's first allegedly misleading statement was its October 22, 2003, press release, announcing the 163% net sales increase, attributed to Zicam, and stating that the Zicam brand was "poised for growth." The second statement was the conference call on October 23, 2003, again attributing the company's positive results to Zicam and projecting further growth. By the time of the press release and the conference call, Hirsch had called the customer service line regarding one patient, Clarot had spoken

with Linschoten regarding customer complaints, Jafek had presented his report of eleven patients, and the first lawsuit against Matrixx had been filed. Appellees accordingly were aware of at least fourteen complaints regarding Zicam and anosmia at the time they made these statements. In addition, Appellants alleged that Clarot told Linschoten in the September 2002 phone call that "Matrixx had received customer complaints of loss of smell as early as 1999." Appellants then alleged that the November 12, 2003, Form 10-Q was misleading because it spoke of the risk of product liability actions against the company without revealing that a lawsuit already had been filed.[7]

In *Berson v. Applied Signal Tech., Inc.*, 527 F.3d 982 (9th Cir. 2008), the defendants argued that a passage in the company's SEC filings regarding backlogged work alerted reasonable investors to the risk that the company might not get paid for work that had actually been stopped. We rejected the argument, stating that "[t]he passage . . . speaks entirely of as-yet unrealized risks and contingencies. Nothing alerts the reader that some of these risks may already have come to fruition, and that what the company refers to as backlog includes work that is substantially delayed and at serious risk of being cancelled altogether." Id. at 986. We therefore disagreed with the district court's finding that the statements were not misleading, reasoning that,

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[7] As Matrixx later admitted, up to and including the class period, Matrixx had conducted no studies on the safety of Zicam regarding any link to anosmia.

"once defendants chose to tout the company's backlog, they were bound to do so in a manner that wouldn't mislead investors as to what that backlog consisted of." *Id.* at 987; *cf. In re Elan Corp. Sec. Litig.*, 543 F. Supp. 2d 187, 208 (S.D.N.Y. 2008) ("By choosing to speak about the safety of [their drug], Defendants assumed a duty to disclose material information regarding adverse events."). After addressing scienter and loss causation, we reversed the district court's dismissal of the complaint. *Berson*, 527 F.3d at 987- 90.

Similar to *Berson*, the passage in the Form 10-Q speaks about the risks of product liability claims in the abstract, with no indication that the risk "may already have come to fruition." *Id.* at 986. At the time that Appellees filed the Form 10-Q, the CAC alleges facts sufficient for a jury to find that Clarot was aware of the potential anosmia problem. Moreover, the inference that high-level executives such as Johnson, Hemelt, and Clarot would know that the company was being sued in a product liability action is sufficiently strong to survive a motion to dismiss.

In response to the January 30, 2004, article in the Dow Jones Newswires that the FDA was investigating complaints of anosmia linked to Zicam, Matrixx issued a press release on February 2, 2004. By the time of this press release, three more lawsuits regarding anosmia had been filed against Matrixx. This press release cites the two double-blind studies regarding the "safety and efficacy of zinc gluconate for the treatment of symptoms related to the common cold," but, again, the press release did not say whether Matrixx studied the intranasal use of zinc gluconate for safety, as opposed to efficacy.

The press release also states that "statements alleging that intranasal Zicam products cause anosmia . . . are completely unfounded and misleading," and then devotes three paragraphs to discrediting the author of the article and urging Dow Jones to investigate the author.

By the time of the February 2, 2004 press release, a strong inference can be drawn that Appellees knew that the statements alleging a link between Zicam and anosmia were not "completely unfounded and misleading." Appellees allegedly knew about the presentation by Jafek to the American Rhinologic Society, Clarot's conversation with Linschoten, and several lawsuits alleging that Zicam caused anosmia. In addition, Matrixx's statements in the press release, that Zicam's safety was "well established" by their trials, conflict with the allegations that Clarot told Linschoten in September 2002 that Matrixx had not conducted any studies and asked her to participate in studies. The references in the press release to clinical trials establishing Zicam's safety also conflict with the March 4, 2004, news report that Matrixx did not know if Zicam could cause anosmia and formed a medical advisory panel to conduct studies.

Matrixx's February 6, 2004, press release, following the *Good Morning America* segment regarding Jafek's findings, repeated the statements that the safety of zinc gluconate to treat cold symptoms had been established in clinical trials, stated that the common cold affects the sense of smell, and stated that the studies linking zinc to anosmia were conducted in the 1930s using a different zinc compound. Matrixx 2/6/2004 press release.

Appellants have not alleged that Appellees engaged in unusual or suspicious stock sales at the same time that they were attempting to downplay the reports of anosmia. *See Silicon Graphics*, 183 F.3d at 986 (stating that "unusual or suspicious stock sales by corporate insiders may constitute circumstantial evidence of scienter") (internal quotation marks omitted). The Supreme Court has stated, however, that, "[w]hile it is true that motive can be a relevant consideration, and personal financial gain may weigh heavily in favor of a scienter inference, we agree with the Seventh Circuit that the absence of a motive allegation is not fatal." *Tellabs*, 551 U.S. at 324.

On a holistic review of the CAC, the following picture is alleged. Matrixx received some customer complaints about Zicam and anosmia from 1999 to 2002. In 2002, Clarot was sufficiently concerned that he called Linschoten about one of her patients who had complained and then called to ask if she would participate in studies. In September 2003, Matrixx knew that Jafek and his colleagues were presenting findings about ten or eleven patients who developed anosmia after Zicam use and did not allow Jafek to use Matrixx's or Zicam's name in the presentation. In October 2003, Matrixx touted the potential for growth and profitability of Zicam in a press release and an earnings conference call. A lawsuit alleging anosmia in one Zicam user was filed in October 2003. In November 2003, Matrixx filed a Form 10-Q, but did not disclose the lawsuit in the section entitled "Risk Factors." More lawsuits were filed in December 2003 and January 2004.

On February 2, 2004, Matrixx issued a press release responding to the January 30, 2004, Dow

Jones report that the FDA was investigating Zicam and anosmia. This press release called the report "completely unfounded and misleading" and asserted that clinical trials had established the safety of zinc gluconate. On February 6, 2004, *Good Morning America* reported on the possible link between Zicam and anosmia, and Matrixx issued another press release asserting that zinc gluconate's safety was well established in clinical trials, even though it was subsequently reported that Matrixx had not conducted such studies. In a February 19, 2004, filing with the SEC, Matrixx stated that it had convened a panel of physicians and scientists to review the information and asserted that there was insufficient evidence to determine whether zinc gluconate affected the sense of smell. On March 4, 2004, a news article reported that Matrixx would begin studies to determine if Zicam caused anosmia.[8]

Viewing the CAC as a whole, the inference of scienter is "cogent and at least as compelling" as any "plausible non-culpable explanation[ ]" for Appellees' conduct. *Tellabs*, 551 U.S. at 324. Withholding reports of adverse effects of and lawsuits concerning the product responsible for the company's remarkable sales increase is "an extreme departure from the standards of ordinary care" and "presents a danger of misleading buyers or sellers." *Silicon*

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[8] We do not address Appellants' allegations that Appellees violated GAAP and FASB principles in the November 12, 2003, Form 10-Q. "Violations of GAAP standards can . . . provide evidence of scienter," but the violations must be described with sufficient particularity. *Daou*, 411 F.3d at 1016.

Graphics, 183 F.3d at 976. We therefore conclude that the inference that Appellees withheld the information intentionally or with deliberate recklessness is at least as compelling as the inference that Appellees withheld the information innocently.

CONCLUSION

The district court's reliance on the statistical significance standard to conclude that Appellants failed to establish materiality is inconsistent with the Supreme Court's rejection of bright-line rules and its emphasis on having materiality determined by the trier of fact. Viewing the CAC in the light most favorable to Appellants, we conclude that Appellants have sufficiently pled materiality to survive dismissal. Similarly, the inference that Appellees withheld the information regarding Zicam and anosmia intentionally or with deliberate recklessness is at least as compelling as any plausible nonculpable explanation. For the foregoing reasons, the judgment of the district court is **REVERSED** and the case **REMANDED** for further proceedings consistent with this opinion.

REVERSED and REMANDED.

APPENDIX B

DISTRICT COURT OPINION

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

James V. Siracusano, on Behalf of Himself, and All Other Similarly Situated, Plaintiff, vs. Matrixx Initiatives, Inc.; Carl J. Johnson; William J. Hemelt; and Timothy L. Clarot, Defendants.	No. CIV-04-0886-PHX-MHM No. CIV-04-1012-PHX-MHM **(consolidated)** **ORDER**

This is a securities fraud case brought pursuant to the Private Securities Litigation Reform Act of 1995 ("Reform Act"). Currently before the Court are Defendant's Motion to Strike, (Dkt. #72); and Defendants' Motion to dismiss. (Dkt. #73). After reviewing the motions and hearing oral argument on October 13, 2005, the Court issues the following Order.

I. Factual and Procedural Background

Defendant-Matrixx Initiatives Inc., ("Matrixx") develops and markets over-the-counter pharmaceuticals. Zicam, Matrixx's wholly-owned subsidiary, produces Zicam Cold Remedy. Between October 22, 2003 and February 6, 2004 ("Class Period"), Plaintiffs purchased thousands of Matrixx shares and instituted this class action on behalf of all purchasers during the Class Period. Am. Compl. ¶ 1. Plaintiffs allege that Matrixx and its officers violated the Securities and Exchange Act by issuing materially false and misleading statements concerning Zicam. Specifically, Plaintiffs assert Matrixx knew that Zicam may cause users to suffer a total and permanent loss of smell, known as anosmia. Further, Plaintiffs assert that while Matrixx warned investors that there was a potential for such lawsuits, Matrixx materially misled investors by not alerting them that such lawsuits had already been filed.

Plaintiffs allege in 1999 Dr. Alan Hirsh M.D., Neurological Director of the Smell & Taste Treatment and Research Foundation, Ltd., recognized a link between Zicam use and anosmia and reported the possible link to Matrixx's customer service line and to a Mr. Landau, *Id.* at ¶ 25. In September 2002, Timothy L. Clarot, Matrixx's Vice President and Miriam R. Linchosten, Ph.D., of the University of Colorado, corresponded regarding a Zicam user complaining of anosmia and regarding studies linking zinc sulfate to anosmia. Id. at ¶¶ 26, 27. In September 2003, a collaborative research effort by medical researchers at the University of Colorado School of Medicine, Department of Otolaryngology, et al. ("University of Colorado

Study") identified 11 Zicam users who had suffered from anosmia. Am. Compl. ¶¶ 3, 24, 28. As of April 2004, Doctor Jafek had evaluated over 100 cases of anosmis and Dr. Linchosten estimated she had treated 65 users of Zicam who suffered from anosmia. *Id.*

Defendants did not disclose the University of Colorado study and instead informed Dr. Bruce Zafek, of the University of Colorado, that "as a legal matter [the University of Colorado] did not have [Matrixx's] permission to use their company name or product trademarks" in association with the University of Colorado study. *Id.* at ¶¶ 4, 29. Plaintiffs contend despite knowledge of the risk of anosmia, Defendants continued to make positive statements regarding Matrixx's growth and revenue and Zicam's safety. Specifically, on October 22, 2003, Matrixx issued a press release indicating net sales increased by 164% by the third quarter of 2002 and stating "[t]he Zicam brand is poised for growth in the upcoming cough and cold season" and the Zicam brand is relied on "as an efficacious product." *Id.* at 32. Again, on October 23, 2003 in a conference call with financial analyst, Defendant Johnson stated "we are extremely encouraged at this point . . . what lies beyond these results is a unique product in the Zicam product line. A product that offers a unique benefit, the ability for consumers to actually reduce the duration and severity of the common cold, not just mask the symptoms." *Id.* at 33.

In a November 12, 2003 quarterly report, Defendants reiterated positive projections with a disclaimer "We may incur significant costs resulting from product liability claims." *Id.* At 35. On February 2, 2004, Plaintiff Matrixx issued a press

release stating:

> Matrixx believes statements alleging that intranasal Zicam products cause anosmia (loss of smell) are completely unfounded and misleading. In no clinical trial of intranasal zinc gluconate gel products has there been a single report of lost or diminished olfactory function. Rather, the safety and efficacy of zinc gluconate for the treatment of symptoms related to the common cold have been well established in two double-blind, placebo-controlled, randomized clinical trials. In fact, in neither study were there any reports of anosmia related to the use of this compound

Id. at 38

On January 30, 2004 an article published in the *Dow Jones Wire* indicated three product liability suits related to the use of Zicam had been filed. *Id.* at ¶¶ 6, 40. On February 2, 2004, Matrixx representatives issued a press release stating that "statements alleging intranasal Zicam products cause anosmia are completely unfounded and misleading." *Id.* at ¶ 6 Additionally Matrixx stated "[i]n no clinical trial of intranasal zinc gluconate gel products [active ingredient in Zicam] has there been a single report of loss or diminished olfactory function." *Id.*

On February 6, 2004, *Good Morning America* reported the University of Colorado study demonstrated Zicam may cause users to suffer from anosmia, four product liability lawsuits related to Zicam users suffering from anosmia were pending, and similar lawsuits were expected. *Id.* at ¶¶ 8,42. The lawsuits were filed from October 2003 to

January 2004. *Id.* at 49. Also on February 6, 2004, Matrixx issued a press release entitled "Reaffirm[ing] safety of intranasal Zicam Cold Remedy" and reiterating that there had been no clinical trial of intranasal zinc gluconate gel causing anosmia. *Id.* at ¶ 9. On February 5, 2004, after the *Good Morning America* broadcast, the price of Matrixx common stock fell 23.8%. *Id.* at ¶¶ 8,43. After meeting with physicians, on February 19, 2004, Defendants filed a Form 8-K with the Security Exchange Commission ("SEC") stating "[i]n the opinion of the panel, there is insufficient scientific evidence at this time to determine if zinc glutonate, when used as recommended, affects a person's ability to smell." *Id.* at ¶ 46.

Also, during the Class Period, Plaintiffs allege Defendants falsely reported Matrixx's profits for the third quarter of 2003 in violation of Generally Accepted Accounting Principals ("GAAP"). Specifically, Plaintiffs contend Defendants failed to disclose that several product liability lawsuits had been filed against Matrixx, which were known contingencies and should have been disclosed. *Id.* ¶¶ 50-57.

Defendants move to dismiss Plaintiffs' first amended complaint on the grounds that plaintiffs have failed to state a claim for relief under Rule 12(b)(6), Federal Rules of Civil Procedure, and have failed to plead with particularity as required by Federal Rule of Civil Procedure 9(b) and the Private Securities Litigation Reform Act of 1995 (Reform Act), 15 U.S.C. § 78u-4.

II. Motion to Strike

A. Legal Standard

Fed. R. Civ. P. 12(f) provides that a party may bring a motion to strike to request the Court to remove insufficient defenses as well as "redundant, immaterial, impertinent, or scandalous matter" that might otherwise prejudice a party. *E.g., Fantasy, Inc. v. Fogerty*, 984 F.2d 1524, 1527 (9th Cir.1993), *rev'd on other grounds*, 510 U.S. 517 (1994). Motions to strike are disfavored because they are "often used as delaying tactics, and because of the limited importance of pleadings in federal practice." *Colaprico v. Sun Microsystems, Inc.*, 758 F. Supp. 1335, 1339 (N.D. Ca1.1991). However, the Court may grant a motion to strike if the party can establish that the statements at issue would prejudice the moving party, or that striking the statements would streamline the case. *Fogerty*, 984 F.2d at 1528.

B. Discussion

Defendants argue the Court should strike Paragraphs, 30, 49, and 64 of the First Amended Complaint because these paragraphs contain allegations after the close of the Class Period. These paragraphs generally include allegations regarding post-Class Period Zicam user complaints of anosmia, post-Class Period studies linking Zicam use to anosmia, and post-Class Period product liability lawsuits.

Courts in this circuit have stricken as irrelevant claims in a complaint alleging fraud and insider trading outside of the class period. *See In re Clearly Canadian Sec. Litig.*, 875 F. Supp. 1410, 1420 (N.D.

Cal. 1995). Furthermore, Congress enacted the Reform Act to put an end to the practice of pleading "fraud by hindsight." *See e.g., Medhekar v. United States Dist. Ct.*, 99 F.3d 325, 328 (9th Cir. 1996) (holding that Congress intended for complaints under the Reform Act to stand or fall based on the actual knowledge of the plaintiffs rather than information produced after the action has been filed).

However, "[a]lthough the class period here is short and definite, it does not determine the period of relevancy for discovery purposes. There are numerous instances in securities fraud litigation where post-offering statements, documents, or conduct have been treated as admissible evidence on the issue of scienter, intent, and knowledge." *In re Seagate Technology II Sec. Litig.*, No, C-89-2493, 1993 WL 293008, *2 (N.D. Cal. Jun 10, 1993) (unpublished opinion).

Here, the relevant inquiry is not whether, in fact, there is a statistically significant link between Zicam use and anosmia. Instead, the inquiry is whether Defendants knew that their statements were false at the time they were made. *In re Silicon Graphics Inc. Sec. Litig.*, 183 F.3d 970, 988 (9th Cir. 1999). Facts related to the post-Class Period research and links between Zicam and anosmia go to the former question and are irrelevant because they have no bearing on whether the Defendants knew there was a statistically significant link at the time of public disclosures. However, facts related to the numerosity of user complaints and lawsuits known to University of Colorado researchers may very well be relevant to Defendant's knowledge of user complaints.

Therefore, the Court will deny the motion to strike paragraphs 30, 49, and 64, in relation to the number of complaints and lawsuits as the Court has concluded that complaints and lawsuits may very well be relevant to Defendants' knowledge of user complaints. However the Court will grant the motion to strike portions of Paragraph 30 & 64 as they relate to Dr. Jafek's ultimate conclusions, published post-Class Period, because what Dr. Jafek's study may ultimately show is not relevant to what Defendants knew at the time statements were made and is highly prejudicial.

III. Standard of Review

Under FED. R. CIV. PRO. Rule 12(b)(6), the court will not dismiss a complaint unless it appears beyond a doubt that the plaintiff can prove no set of facts to support the claim that would entitle the plaintiff to relief. *Morley v. Walker*, 175 F.3d 756, 759 (9th Cir. 1999). In determining whether a complaint states a claim, all allegations of material fact are taken as true and construed in the light most favorable to the nonmoving party, her Plaintiffs. *Wyler Summit P'ship v. Turner Broad. Sys., Inc.*, 135 F.3d 658, 661 (9th Cir. 1998). However, "the court [is not] required to accept as true allegations that are merely conclusory, unwarranted deductions of fact, or unreasonable inferences." *Sprewell v. Golden State Warriors*, 266 F.3d 979, 988 (9th Cir. 2001). Additionally, while the Court's primary focus is on allegations contained in the pleadings, the Court may also consider documents attached to the complaint or incorporated by reference. *In re Northpoint Communications Group, Inc.*, 221 F. Supp. 2d 1090 (N.D. Cal. 2002).

Furthermore, judicial notice of documents filed with the Security Exchange Commission is proper in actions alleging securities fraud. *See e.g., Allison v. Brooktree Corp.*, 999 F. Supp. 1342, 1352 n.3 (S.D. Cal. 1998).

Rule 9(b) also imposes particularized pleading requirements on a plaintiff alleging fraud or any claim premised on fraud such that all averments of fraud or mistake must be stated with particularity. Fed. R. Civ. Pro. 9(b) (2005). Additionally, an action brought under the Reform Act is subject to heightened pleading standards that are more rigorous than the Rule 9(b) standards. The Reform Act requires the plaintiff to "specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information or belief, the complaint shall state with particularity all facts on which that belief is formed." 15 U.S.C. § 78u-4(b)(1). The complaint must also state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind with respect to each act or omission alleged to violate securities law. 15 U.S.C. § 78u-4(b)(2). The required state of mind is deliberate recklessness. *In re Silicon Graphics Inc. Sec. Litig.*, 183 F.3d 970, 977 (9th Cir. 1999). However, if the alleged material false statement or omission is a "forward-looking statement," the required level of scienter is actual knowledge. 15 U.S.C. § 78u-5(c)(1)(B). A motion to dismiss the complaint must be granted if the complaint fails to satisfy these requirements. 15 U.S.C. § 78u-4(b)(3)(A).

In addition, the plaintiff has the burden of proving that the act or omission of the defendant

caused the loss for which the plaintiff seeks to recover damages. 15 U.S.C. § 78u4(b)(4). Section 10(b) makes it unlawful for any person "to use or employ, in connection with the purchase or sale of any security ... any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the [Securities and Exchange] Commission may prescribe as necessary or appropriate ...." 15 U.S.C. § 78j(b). Rule 10b-5 makes it unlawful to "make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading[.]" 17 C.F.R. § 240.10b-5(b).

IV. Discussion

To state a securities fraud claim, a plaintiff must allege that a defendant: (1) made a misrepresentation of fact or an omission (2) of a material fact; (3) with scienter; i.e., intent to deceive; (4) in connection with the purchase and sale of a security; (5) upon which the plaintiff relied; and (6) that the plaintiff's reliance was the proximate cause of the injury for which plaintiff seeks to recover damages. Securities Exchange Act of 1934, § 10b; *DSAM Global Value Fund v. Altris Software, Inc.*, 288 F.3d 385, 388 (9th Cir. 2002).

A. Misstatement or Omission of Material Fact

Under the Reform Act, to adequately allege securities fraud a complaint must specify each statement alleged to have been misleading, the reason or reasons why the statement was misleading and, if an allegation is made on information and

belief, all facts upon which that belief is formed. 15 U.S.C. 78u-4(b)(1). An omission is actionable under Section 10(b) if the omitted fact is material – that is, its disclosure to necessary to prevent another statement from being materially misleading. Id. Plaintiffs allege two general categories of statements and omissions prior to the end of the class period are actionable: statements regarding the safety of Zicam without disclosing a link between Zicam and anosmia and statements related to Zicam's commercial and financial potential. In essence, Plaintiffs contention is Defendants' knowledge of the University of Colorado study, user complaints, and four product-liability class actions gave rise to a duty to disclose and correct statements relating to Zicam's safety, profitability, and especially statements that there had been no clinical trial showing intranasal zinc gluconate gel causes anosmia.

In a similar context, courts have found adverse information related to the safety of a product is not material unless such reports provide reliable statistically significant information that a drug is unsafe. *In re Carter-Wallace, Inc.*, 220 F.3d 36 (2d. Cir. 1998). *Carter-Wallace* involved a securities fraud claim, alleging that Carter-Wallace had run advertisements in medical journals in the first months of 1994 regarding its new epilepsy drug, Felbatol, and had made representations in these advertisements about the safety of the drug and the lack of adverse side effects. The complaint alleged that these representations were made despite the fact that Carter-Wallace was receiving medical reports that some patients using Felbatol had developed illnesses, including aplastic anemia, a fatal disease. Additional reports of aplastic anemia

were received in July 1994 resulting in a letter issued by Carter-Wallace and the Food and Drug Administration on August 1, 1994 recommending to doctors immediate withdrawal of patients from treatment with the drug. Following the letter there was a substantial drop in the price of Carter-Wallace common stock.

The plaintiffs in *Carter-Wallace* complained about the failure to disclose the adverse medical reports which were received before July 1994, and alleged that such failure indirectly inflated the market price of the Carter-Wallace stock. The Second Circuit held that there was no sufficient allegation of a knowing withholding of material information. There was no indication, said the court, that Carter-Wallace knew, or should have known, before August 1, 1994, of the connection between Felbatol and aplastic anemia. *Carter-Wallace, Inc.*, 220 F.3d at 42. The court stated: "Here, the early medical reports may have indicated a potential problem, but until a connection between Felbatol and any illness could be made, we would not expect Carter-Wallace to abandon its product on what, at the time, would have been speculation." *Id.* The court took the view that Carter-Wallace was not dishonest or reckless in viewing the earlier reports as merely "random" instances of disease (i.e., not necessarily caused by Felbatol). The court noted: "Felbatol had, after all, survived the extensive testing process required by the FDA. *Id.* The court also stated that "Carter-Wallace's financial statements would not ... become materially misleading until Carter-Wallace had information that Felbatol had caused a *statistically significant* number of aplastic anemia deaths and therefore had

reason to believe that the commercial viability of Felbatol was threatened." *Id.* at 40 (emphasis added)

While, subsequent courts have noted *Carter-Wallace* does not provide a "bright-line pleading standard" for securities fraud claims where those claims are "based upon alleged failure to disclose adverse medical reports," other circuits have followed the reasoning in *Carter-Wallace*, concluding that Defendants must have statistically significant information before statements related to a products drug safety become material. *Oran v. Stafford*, 226 F.3d 275, 284 (3d. Cir. 2000) (holding "[b]ecause the link between the . . . drugs and heart-valve disorders was never definitively established during the relevant period even after the withdrawal data is taken into account [defendant's] failure to disclose this data cannot render its statements about inconclusiveness of the relationship materially misleading"); *see also In re Alliance Pharm. Sec. Litig.*, 279 F. Supp. 2d 171, 189 (finding there was a genuine issue of material fact regarding whether failure to include information in prospectus that test group would change in composition was a material omission, after noting "not every adverse effect in a clinical trial is automatically material, and that causation, as well as statistical significance, is key").

However, where a company is presented with statistically significant adverse medical reports, adverse clinical data, and a "consensus emerge[s] that the data" is "putting the brand at risk," then courts have found a material omission. *In re Bayer AG Sec. Litig.*, No 03 C1V.1546 WHP, 2004 WL 2190357, *4 (S.D.N.Y. Sept. 20, 2004) (unpublished opinion). In *Bayer AG*, Defendants received

repeated and numerous adverse event reports indicating its drug Baycol, a cholesterol-lowering drug, caused rhabdomyolysis, an acute sometimes fatal serious muscle disease. However, Defendants repeatedly touted the efficacy, safety, and profitability of Baycol. In fact, the District Court noted by 1999 "adverse event reports were inundating Bayer" with 60 cases of rhabdomyolysis in the preceding 2 months in the United States. Id. Still, the District Court concluded Defendants only had a duty to correct previous statements as to Baycol's safety and future profitability as of August 2000, when Bayers' consultants met and "a consensus emerged that the data concerning Baycol's dangers 'was putting the brand at risk.'" The District Court reasoned it was only after the consensus emerged was the data on Baycol "sufficiently serious and frequent to affect future earnings." *Id.* at *10; *see also DeMarco v. DepoTech Corp.*, 32 Fed. Appx. 260 (9th Cir. 2002) (complaint failed to satisfy Reform Act pleading requirements where it alleged merely that drug manufacturing company's officers made positive statements about product's prospects after receiving negative clinical trial reports and failed to particularly identify which reports were contradicted by contemporaneous positive statements, nor any details as to how officers were made aware of said reports).

The above cases recognize that test results and user complaints are not always material, requiring disclosures. "Medical researchers may well differ with respect to what constitutes acceptable testing procedures, as well as how best to interpret data garnered under various protocols." *Pasnes v. Scios Nova Inc.*, No C 95-1693, 1996 WL 539711 *5 (N.D.

Cal. Sept. 18, 1996). The Food and Drug Administration ("FDA") similarly recognizes that experts can find test results difficult to interpret. In explaining to Congress why the FDA insists that applicants provide all test data to the agency instead of only summaries, that agency has stated:

> summary data has necessarily been processed, and that processing includes interpretation. When data is summarized, a decision must have already been made to look at it in some particular way. A review of the actual data provides the opportunity for that data to reveal information that would not be evidence from the single perspective.

Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations for 1997,: Hearing Before Subcomm. of the House Comm. on Appropriations, 104th Cong., 2d Sess. at 512 (1996) (written responses by FDA to questions from Congresswoman Kaptur).

Similarly, Matrixx conducted a double-blind study regarding Zicam and not a single case of anosmia was reported. The Amended Complaint provides the following allegations of links between Zicam and anosmia for which Defendants had knowledge: a phone conversation between a Matrixx vice-president and University of Colorado researcher discussing one anosmia complaint, a 1999 study recognizing a possible link, and a University of Colorado study citing 11 cases of anosmia in Zicam users. Similar to *Carter-Wallace*, Plaintiffs present minimal evidence of Zicam complaints during the class period. Zicam is a homeopathic remedy, and therefore is not subject to the same FDA approval as

in *Carter-Wallace*. Nonetheless, the Court finds the adverse medical reports of Felbatol and user complaints here analogous. Simply, there is no data as to the reliability and accuracy of the user complaints. Even if there were data as to the reliability, the Court finds 12 user complaints is not statistically significant. While the Complaint cites to 165 other complaints, it fails to allege those user complaints were within the class period or that Defendants had any knowledge of the complaints. Moreover, Plaintiffs have failed to allege that during the class period, Defendants were presented with any evidence that the University of Colorado study was reliable, the methodology used, or that it was subject to peer review. Based on the foregoing, the Court finds that as of the close of the class period, Plaintiffs have failed to present evidence of a statistically significant correlation between the use of Zicam and anosmia so as to make failure to publically disclose complaints and the University of Colorado study a material omission.

B. Scienter

The complaint must also state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind with respect to each act or omission alleged to violate securities law. 15 U.S.C. § 78u-4(b)(2). The required state of mind is deliberate recklessness. *In re Silicon Graphics Inc. Sec. Litig.*, 183 F.3d 970, 977 (9th Cir. 1999). However, if the alleged material false statement or omission is a "forward-looking statement," the required level of scienter is actual knowledge. 15 U.S.C. § 78u-5(c)(1)(B).

Furthermore, the Reform Act modifies the

traditional standard 12(b)(6) – taking all allegations of material fact as true and in the light most favorable to the nonmoving party. *Gompper v. VISX Inc.*, 298 F.3d 893, 897 (9th Cir. 2002). Instead, the Ninth Circuit has held, "when determining whether plaintiffs have shown a strong inference of scienter, the court must consider all reasonable inferences to be drawn from the allegations, including inferences unfavorable to the plaintiffs." *Id.*

Even if the Court were to find an actionable omission or misrepresentation, the Court concludes the First Amended Complaint fails to allege the requisite scienter. Plaintiffs argue the Defendants acted with deliberate recklessness when failing to disclose a known link between Zicam and anosmia to falsely inflate the price of stock. Additionally, failure to disclose product liability lawsuits as a known contingency is a violation of GAAP and evidence of deliberate recklessness.

Here, the Complaint fails to allege any motive or state of mind with relation to the alleged omissions. Plaintiffs argue that Defendants actions in informing Dr. Jafek, that the University of Colorado did not have permission to use Zicam marks is evidence of scienter. However, the argument is not well taken. It is just as reasonable to infer, Defendants were appropriately protecting Zicam's good name and marketability. Furthermore, in the letter from an Allied Waste researcher informing Dr. Jafek he did not have permission to use Zicam marks, Mr. Clarot stated "we are very much interested in learning more about adverse reports included in your presentation and, to the extent you have valid clinical data supporting your conclusions, we would appreciate receiving that immediately."

Longo Decl. Ex. 1. There are no allegations Defendants disbelieved their statements as to the safety of Zicam, Defendants profited, or attempted to profit from public statements.

Furthermore, per se violations of GAAP and generally accepted standards for financial reporting alone are insufficient to state a claim for securities fraud, though evidence of the foregoing could support a strong inference of scienter when combined with other circumstances establishing fraudulent intent. *In re Commtouch Software Ltd. Sec. Litig.*, Fed. Sec. L. Rep. (CCH) ¶ 91985, 2002 WL 31417998 (N.D. Cal. 2002) (concluding complaint alleging corporation engaged in a pattern of recording revenue without regard to its ability to collect revenue stated fraud claim with requisite particularity; confidential witnesses described specific conduct which raised strong inference of at least actionable deliberate recklessness). Such circumstances include overstatements of earnings so vast as to be deliberately false and misleading with respect to the issuer's financial condition, or underreporting of accounts payable and other liabilities in such a magnitude that the intent to mislead the investing public about the issuer's financial condition clearly can be inferred. *Marksman Partners, L.P. v. Chantal Pharm. Corp.*, 927 F. Supp. 1297, 1313 (C.D. Cal. 1996) (holding "a violation of GAAP, in itself will generally not be sufficient to establish fraud, when combined with other circumstances suggesting fraudulent intent, however, allegations of improper accounting may support a strong inference of scienter"). Here, as noted above, other than the conclusory allegation there was a duty to disclose the one product liability

lawsuit filed at the time of the third quarter 10-Q. Plaintiffs have failed to allege a loss was reasonable foreseeable or any other overstatement giving rise to an inference of deliberate recklessness.

FED R. CIV. PRO. 15 provides that leave to amend complaints "shall be freely granted." As a general rule, it is an abuse of discretion for the district court to dismiss the plaintiff's complaint without first affording opportunity for amendment to state a claim for which relief can be granted. Absent unusual circumstances, "[d]ismissal without leave to amend is improper unless it is clear, upon de novo review, that the complaint could not be saved by any amendment." *Polich v. Burlington Northern, Inc.*, 942 F.2d 1467, 1472 (9th Cir. 1991). While some circuits have concluded the Reform Act has modified Rule 15's leave to amend with extreme liberality, the Ninth Circuit has held "[d]ismissal with prejudice and without leave to amend is not appropriate unless it is clear on de novo review that the complaint could not be saved by amendment." *Eminence Capital, LLC v. Aspeon, Inc.*, 316 F.3d 1048, 1052 (9th Cir. 2003).

Given the fact Plaintiffs have alleged 165 user complaints in the First Amended Complaint, that the University of Colorado study was ultimately peer reviewed, and Defendants' knowledge during the Class Period is unclear, the Court will dismiss the First Amended Complaint without prejudice. However, Plaintiffs should take note that allegations of post-Class period user complaints, post-Class Period links between Zicam and anosmia, and post-Class Period publication of the University of Colorado study, lending it credibility, are wholly insufficient to cure the deficiencies in the First

Amended Complaint. Absent allegations Defendants *knew* there was a definitive and statistically significant link between Zicam and anosmia *during the Class Period* that was "sufficiently serious and frequent to affect future earnings," any amendment would be futile.

Accordingly

IT IS HEREBY ORDERED Defendants' Motion to Strike is **GRANTED IN PART AND DENIED IN PART**. (Dkt. #72)

IT IS FURTHER ORDERED Defendants' Motion to dismiss is **GRANTED.** The First Amended Complaint is dismissed **WITHOUT PREJUDICE.** (Dkt. #73).

DATED this 15th day of December, 2005.

Mary H. Murguia
United States District Judge

APPENDIX C

COURT OF APPEALS REHEARING DENIAL

FILED

DEC 23 2009

MOLLY C. DWYER, CLERK
U.S. COURT OF APPEALS

NOT FOR PUBLICATION

UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

JAMES SIRACUSANO, Individually and on behalf of all others similarly situated, Plaintiff - Appellant, NECA-IBEW PENSION FUND, Claimant - Appellant, v. MATRIXX INITIATIVES, INC.; CARL J. JOHNSON; WILLIAM J. HEMELT, Defendants - Appellees.	No. 06-15677 DC Nos. CV 04-0886 MHM CV 04-1012 MHM O R D E R

Before: SCHROEDER, TASHIMA and BEA,

Circuit Judges.

The panel has voted to deny the petition for panel rehearing. Judges Schroeder and Bea vote to deny the petition for rehearing en banc and Judge Tashima so recommends. The full court has been advised of the petition for rehearing en banc and no judge of the court has requested a vote on en banc rehearing. *See* Fed. R. App. P. 35(f). The petition for panel rehearing and the petition for rehearing en banc are denied.

APPENDIX D

STATUTORY & REGULATORY PROVISIONS

15 U.S.C. § 78j(b) - Manipulative and Deceptive Devices

It shall be unlawful for any person, directly or indirectly, by the use of any means or instrumentality of interstate commerce or of the mails, or of any facility of any national securities exchange--

***

(b) To use or employ, in connection with the purchase or sale of any security registered on a national securities exchange or any security not so registered, or any securities-based swap agreement (as defined in section 206B of the Gramm-Leach-Bliley Act), any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the Commission may prescribe as necessary or appropriate in the public interest or for the protection of investors.

15 U.S.C. § 78u-4(b)(2) - Private Securities Litigation

(b) Requirements for securities fraud actions

***

(2) Required state of mind

In any private action arising under this chapter in which the plaintiff may recover money damages only on proof that the defendant acted with a particular state of mind, the complaint shall, with respect to

each act or omission alleged to violate this chapter, state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind.

SEC Rule 10b-5 - Employment of Manipulative and Deceptive Devices

It shall be unlawful for any person, directly or indirectly, by the use of any means or instrumentality of interstate commerce, or of the mails or of any facility of any national securities exchange,

(a) To employ any device, scheme, or artifice to defraud,

(b) To make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading, or

(c) To engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person, in connection with the purchase or sale of any security.

OPPOSITION BRIEF

Supreme Court, U.S.
FILED
MAY 13 2010
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No. 09-1156

IN THE

Supreme Court of the United States

MATRIXX INITIATIVES INC., et al.,
Petitioners,

v.

JAMES SIRACUSANO AND NECA-IBEW PENSION FUND,
Respondents.

On Petition for Writ of Certiorari To the United States Court of Appeals For the Ninth Circuit

OPPOSITION TO PETITION FOR WRIT OF CERTIORARI

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QUESTIONS PRESENTED

1. Whether the Court of Appeals correctly held that the district court's reliance upon a singular "statistical significance" standard in order to assess the materiality of petitioners' misstatements and omissions was inconsistent with this Court's decision in *Basic Inc. v. Levinson*, 485 U.S. 224 (1988), rejecting bright-line materiality rules.

2. Whether the Court of Appeals correctly held that, in considering all of the alleged facts together and taking them to be true, the Complaint's allegations gave rise to a strong inference of scienter that was cogent and at least as compelling as any opposing inference drawn from the facts alleged.

RULE 29.6 DISCLOSURE

Neither James Siracusano nor NECA-IBEW Pension Fund is a corporation.

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In The

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Matrixx Initiatives Inc., et al.,
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James Siracusano and NECA-IBEW Pension Fund,
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On Petition for Writ of Certiorari
To the United States Court of Appeals
For the Ninth Circuit

OPPOSITION TO PETITION FOR WRIT OF CERTIORARI

I. STATEMENT OF THE CASE

A. Matrixx's Core Business: the Zicam Cold Remedy

Petitioner Matrixx develops, manufactures, and markets over-the-counter pharmaceuticals. ER68:¶2.[1] Matrixx's core brand during the Class Period – through its wholly-owned subsidiary Zicam, LLC – was a line of common-cold products comprising 100% of Matrixx's sales,

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[1] Citations to "ER___" are to the Excerpts of Record filed in the Ninth Circuit Court of Appeals; citations to "App. __" are to the Appendix filed by petitioners. Because the appeals court's opinion does not necessarily list all relevant record facts, respondents will supplement their Appendix cites when required with citations to the operative Complaint ("ER68:¶__").

gross profits, and growth. *Id.*; App. 2a. Within that core product line, "Zicam Cold Remedy" (hereafter "Zicam") accounted for approximately 70% of sales overall. App. 4a. The cold remedy could be applied in several forms, including a nasal spray and nasal gel. *Id.*

It is that intranasal version of Zicam that lies at the center of this action.

B. Petitioners Received Repeated Warnings from Olfactory Medical Researchers and Complaints from Zicam Users that Zicam Caused a Horrific Side Effect Called "Anosmia" – Loss of Sense of Smell – in Numerous Users

Both before and during the Class Period, petitioners received numerous warnings that Zicam nasal gel use was being linked to the loss of sense of smell in some users.

1. Dr. Alan Hirsch, Neurological Director of the Smell & Taste Treatment and Research Foundation, Warned Matrixx in December 1999 About a Zicam-Anosmia Link

In 1999, Dr. Alan Hirsch, M.D., F.A.C.P., recognized a possible link between Zicam nasal gel and loss of smell in "a cluster" of his patients. ER68:¶25; App. 4a-5a. In December 1999 – nearly four years before the Class Period began – Dr. Hirsch called Matrixx's customer service line to inquire about the amount of zinc in Zicam's nasal gel. App. 4a-5a. Dr. Hirsch reported to Matrixx that one of his patients had developed anosmia after using Zicam, and noted that there existed studies demonstrating problems associated with the intranasal application of zinc. App. 5a. Dr. Hirsch volunteered to conduct a clinical study on the possible Zicam-anosmia link, but was turned down. *Id.*

2. Petitioner Clarot Approached Dr. Miriam Linschoten of the University of Colorado's Health Sciences Center and the Rocky Mountain Taste and Smell Center ("RMTSC") in 2002, and Discussed with Her Complaints Matrixx Had Received Concerning the Link Between Zicam Use and Anosmia

Petitioner Timothy Clarot, Matrixx's Vice President of Research and Development, reached out to Dr. Linschoten in September 2002 concerning Zicam's link with anosmia. App. 5a. Clarot had called Dr. Linschoten because one of the several patients she had been treating at the RMTSC for loss of smell following Zicam use had also complained to Matrixx. *Id.* Clarot admitted to Dr. Linschoten that Matrixx had received *additional* similar complaints from other Zicam nasal gel consumers. *Id.* In fact, Matrixx had been receiving those complaints as far back as 1999. *Id.*

Dr. Linschoten followed up Clarot's call by e-mailing him several abstracts on the link between zinc sulfate and anosmia – pointing out that zinc's toxicity had been confirmed by studies dating back to the 1930s. *Id.* In response, Clarot telephoned her again, and invited her to participate in some upcoming animal studies Matrixx was planning. *Id.* Dr. Linschoten declined, explaining that her focus was on human research. *Id.*

3. Dr. Bruce Jafek, in the Department of Otolaryngology at the University of Colorado School of Medicine, Prepared a Medical-Conference Presentation in Fall 2003 that Described Ten Cases of Zicam-Linked Anosmia – and in Response Matrixx Warned Him Against Identifying Zicam

As of September 2003 – just one month before the Class Period – Dr. Jafek had observed ten patients suffering from anosmia following Zicam use. App. 5a-6a. Together with Dr. Linschoten and a second colleague (Bruce Murrow, also from Colorado's Department of Otolaryngology[2] (ER68:¶64)), Dr. Jafek planned to submit the trio's findings via a September 20, 2003 poster presentation to the American Rhinologic Society. App. 5a-6a. Prior to the September conference, the Society posted the scheduled presentations in abstract form. ER68:¶28. The abstract for the Jafek-Linschoten-Murrow presentation was entitled "Zicam® Induced Anosmia." *Id.*

The trio's research included a detailed description of a 55-year-old man who, prior to using Zicam, had normal taste and smell function. *Id.* Upon spraying Zicam into his nose, however, the subject experienced severe burning that was followed immediately by the loss of his sense of smell. *Id.* The Colorado researchers reported "10 [*sic*] other Zicam users with similar symptoms." *Id.*[3]

Before the researchers could make their formal presentation, on September 12, 2003, Matrixx sent a letter to Dr. Jafek – signed by petitioner Clarot – informing him that he could not name either Matrixx or its products on the poster. ER68:¶29; App. 6a. After consulting with the University of Colorado's attorney, Dr. Jafek sought Matrixx's permission to use the names – which Matrixx denied in a second letter. ER68:¶29. Dr. Jafek then cut

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[2] Otolaryngologists are "physicians trained in the medical and surgical management and treatment of patients with diseases and disorders of the ear, nose, throat (ENT), and related structures of the head and neck." *See* the American Academy of Otolaryngology's Web site at http://www.entnet.org/healthinformation/AboutOtolaryngology.cfm.

[3] The Complaint contains a typo, and should have stated that the researchers reported "9 other Zicam users," for a total of 10.

out all instances of the word "Zicam" from the poster, and presented it to the Society in redacted form. *Id.*; App. 6a, 19a.

4. Numerous Zicam Users Filed Personal Injury Lawsuits Against Matrixx, Complaining that Zicam Caused Their Loss of Sense of Smell

Beginning just before and continuing throughout the three-and-a-half-month Class Period, nine Zicam users sued Matrixx for personal injuries – alleging that Zicam had damaged their sense of smell. ER68:¶49; App. 32a.

- On October 14, 2003, two plaintiffs sued Matrixx in Michigan federal court, in *Christensen, et al. v. Matrixx Initiatives, Inc., et al.*, No. 4:03-cv-0146-HWB (W.D. Mich.). ER68:¶49.
- On December 8, 2003, a plaintiff sued Matrixx in California state court, in *Nelson v. Matrixx Initiatives, Inc., et al.*, No. YC048136 (Cal. Super. Ct. – Los Angeles). *Id.*
- On December 18, 2003, a plaintiff sued Matrixx in Alabama state court, in *Sutherland v. Matrixx Initiatives, Inc., et al.*, No. CV2003-1635-WHR (Ala. Cir. Ct. – Etowah). *Id.* The case was later removed to Alabama federal court (No. 4:2004cv00129 (N.D. Ala.). *Id.*
- On January 23, 2004, five plaintiffs sued Matrixx in Arizona state court, in *Bentley, et al. v. Matrixx Initiatives, Inc., et al.*, No. CV2004-001338 (Ariz. Super. Ct. – Maricopa). *Id.* The number of plaintiffs in *Bentley* eventually grew to 266, through consolidation of later suits. *Id.*

The foregoing lawsuits were just the Zicam-related personal injury actions filed before the Class Period's end

on February 6, 2004 – at which point Matrixx was still insisting that Zicam was perfectly safe. ER68:¶44; App. 13a-14a. Matrixx's Securities and Exchange Commission ("SEC") filings later revealed that from late 2003 through October 2004, over 280 individuals sued Matrixx, alleging that Zicam had damaged their sense of smell. App. 16a.

C. Despite the Foregoing, Petitioners Made a Series of False and Misleading Public Reassurances Concerning Zicam's Supposed Safety

Throughout the Class Period, Petitioners issued a series of false and misleading statements concerning Zicam's safety, and what the Zicam product line portended for Matrixx's financial success. ER68:¶¶32-41; App. 6a-14a. The Zicam brand was "poised for growth" in the upcoming cough and cold season, for Matrixx's retail partners had come to rely on the Zicam brand as "an efficacious product." App. 6a-7a. The driving force behind Matrixx's "very strong momentum" heading into the season was the Zicam product line – "a product that offers a unique benefit." App. 7a. Revenues for the full year were poised to rise dramatically, "up in excess of 50%." *Id.*

Notably, on November 12, 2003, Matrixx formally filed its third-quarter 2003 financial results on Form 10-Q with the SEC. App. 8a. Petitioners Johnson and Hemelt both signed the filing. ER68:¶35. Although the *Christensen* lawsuit accusing Zicam of causing anosmia had already been filed the previous month (ER68:¶49), Matrixx's November filing omitted that fact. ER68:¶35; App. 9a.

Instead, Matrixx simply warned investors of the reputational and financial consequences from a *potential* product-liability claim against it – even if the claim was without merit:

> A product liability claim, even one without merit or for which we have substantial coverage, could result in significant legal defense costs, thereby increasing our expenses and lowering our earnings. Such a claim, whether or not proven to be valid, could have a material adverse effect on our product branding and goodwill, resulting in reduced market acceptance of our products. This in turn could materially adversely affect our results of operations and financial condition.

App. 9a. Johnson and Hemelt also signed the quarterly report's certification pursuant to §302 of the Sarbanes-Oxley Act of 2002, asserting that the report did not contain any untrue statements of material fact "or omit to state a material fact necessary to make the statements made" not misleading. ER68:¶36.

D. As Complaints Surfaced About Zicam-Caused Anosmia, Matrixx Went on the Offensive – Vehemently (and Falsely) Denying Any Link Between Zicam and Loss of Sense of Smell

On January 30, 2004, after the close of ordinary trading, the Dow Jones Newswires reported that the Food and Drug Administration ("FDA") was looking into complaints that "an over-the-counter common-cold medicine manufactured" by a Matrixx unit "may be causing some users to lose their sense of smell." App. 10a. Dow Jones noted that the allegations had been made in "at least three lawsuits." *Id.* In fact, by the time of the January 30 Dow Jones piece, ***four*** Zicam-related lawsuits had been filed against Matrixx by nine plaintiffs. ER68:¶49. Following the Dow Jones revelation, Matrixx's stock price dropped from $13.55 per share on January 30, 2004, to $11.97 per share on February 2, 2004. App. 10a.

Matrixx responded to the Dow Jones piece with a

February 2 press release denying any Zicam-anosmia connection. App. 10a-11a. Any statements "alleging that intranasal Zicam products cause anosmia (loss of smell)," blasted Matrixx, "*are completely unfounded and misleading.*" App. 10a (emphasis added). Indeed, "*[i]n no clinical trial* of intranasal zinc gluconate gel products *has there been a single report* of lost or diminished olfactory function (sense of smell). Rather, the *safety and efficacy of zinc gluconate for the treatment of symptoms related to the common cold have been well established* in two double-blind, placebo-controlled, randomized clinical trials." App. 11a (emphasis added). Matrixx suggested the blame might lie elsewhere, as a "multitude of environmental and biologic influences are known to affect the sense of smell." *Id.*

Following Matrixx's denials, its stock price rose back to $13.40 on February 3. App. 13a.

E. Once the Dramatic Truth About Zicam's Link to Loss of Sense of Smell Was Revealed to a Nationwide Audience, Matrixx's Stock Price Plummeted

On February 6, 2004, the link between Zicam and anosmia was revealed to a nationwide television audience. App. 13a. On the news program *Good Morning America* that day, reporter John Ferrugia told viewers about a woman named "Linda" who claimed that Zicam gel had caused her anosmia. ER68:¶42; App. 13a. Ferrugia noted that Linda's claim was not an isolated one: "Dr. Bruce Jafek has discovered more than a dozen patients with the same troubles as Linda . . . after using the Zicam product." ER68:¶42. The reporter also tallied the burgeoning number of lawsuits against Matrixx alleging Zicam-caused anosmia: "[I]n fact, there have been, so far, four lawsuits." *Id.* But those four were not the only ones on the horizon, as "[o]thers are being prepared, anywhere from California to Michigan." *Id.*

Petitioners continued to obfuscate and deny. That same day, Matrixx issued another press release entitled "Reaffirm[ing] Safety of Intranasal Zicam® Remedy," and insisted that any reports linking anosmia with Zicam were "completely unfounded and misleading." ER68:¶44; App. 13a. "In no clinical trial of intranasal zinc gluconate gel products has there been a single report of lost or diminished olfactory function (sense of smell)." App. 13a.

Petitioners' denials did not work this time. Following the *Good Morning America* piece, Matrixx's common stock plummeted from the previous day's $13.05 per share to close at $9.94, on unusually heavy trading volume. ER68:¶43. Investors saw nearly one-quarter of their Matrixx stock value erased, for the plunge represented a one-day drop of 23.8%. *Id.*; App. 13a.

F. Epilogue: Petitioners' Post-Class Period Admissions Contradicted Their Earlier Representations, While the Numbers of Zicam-Related Anosmia Sufferers Climbed Even Higher

In a stunning turnaround from its insistence two weeks earlier that any alleged links between Zicam and anosmia were "completely unfounded and misleading," on February 19, 2004, Matrixx admitted that it simply *did not know* whether or not Zicam could cause loss of sense of smell. ER68:¶¶45-46; App. 14a-15a.

The admission came in a Form 8-K filed with the SEC, in which Matrixx explained that it had convened a two-day meeting of "physicians and scientists to review current information on smell disorders" as a direct response to "a poster presentation at the American Rhinological [*sic*] Society in September 2003." ER68:¶45; App. 14a. The Matrixx-convened panel concluded that there was "*insufficient scientific evidence at this time to deter-*

mine if zinc gluconate, when used as recommended, *affects a person's ability to smell.*" App. 15a (emphasis added). As reporter John Ferrugia noted in a followup report: "All along, Matrixx Initiatives, the maker of Zicam, said the product was safe. But now it admits there are no studies dealing with the issue." ER68:¶47; App. 15a.

As the underlying matter was pending, the FDA issued a warning letter to Matrixx on June 16, 2009, explaining that several Zicam products "may pose a serious risk to consumers who use them."[4] The FDA had received "more than 130 reports of anosmia, (loss of sense of smell, which in some cases can be long-lasting or permanent), associated with use of these products." *Id.* Directly contradicting petitioners' claims of clinical studies establishing Zicam's safety, the FDA noted: "*We are not aware of any data* establishing that the Zicam Cold Remedy intranasal products are generally recognized as safe and effective for the uses identified in their labeling. [footnote omitted] *On the contrary*, as described below, *there is evidence that these products pose a serious safety risk to consumers.*" *Id.* (emphasis added).

II. REASONS FOR DENYING THE PETITION

In order to adequately allege a private securities-fraud violation under §10(b) of the Securities Exchange Act of 1934 and SEC Rule 10b-5, a plaintiff must allege: (1) a material misrepresentation or omission; (2) scienter; (3) a connection with the purchase or sale of a security; (4) reliance (or "transaction causation"); (5) economic loss; and (6) loss causation. *Dura Pharms., Inc. v. Broudo*, 544 U.S. 336, 341-42 (2005).

The district court dismissed respondents' Complaint solely on the grounds that the first two elements had been

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[4] *See* http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm166909.htm.

inadequately alleged.[5] And, as petitioners admit, those two holdings were based upon a single, overlapping rationale: the district court's utilization of a "*statistical significance standard* as a measure of both materiality and scienter." Pet. 5 (emphasis added).

It is that concept of "statistical significance" that the Ninth Circuit correctly rejected as a singular requirement for materiality – harkening to this Court's rule in *Basic Inc. v. Levinson*, 485 U.S. 224, 236 (1988). And, in the Circuit's scienter holding (*see infra* §II.D.), the panel focused on the totality of the Complaint's allegations while answering the question of whether the resulting scienter inference was cogent and at least as compelling as any opposing inference drawn from the facts alleged – just as this Court counsels. *See Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 311 (2007).

A. The Ninth Circuit's Refusal to Apply a Bright-Line Materiality Test Faithfully Comports with This Court's Holding in *Basic Inc. v. Levinson*

Faced with a district-court decision requiring that the "materiality" element of a securities-fraud claim be supported by "statistically significant" information, the Ninth Circuit looked to established materiality precedent while rejecting that bright-line approach. App. 21a-26a.

The *Matrixx* panel explained that this Court in *Basic* "rejected the adoption of a bright-line rule to determine materiality because "'[t]he determination [of materiality] requires delicate assessments of the inferences a 'reasonable shareholder' would draw from a given set of facts

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[5] Because the district court's dismissal hinged on just materiality and scienter, the Ninth Circuit confined its analysis to those two elements. App. 21a.

and the significance of those inferences to him.'" App. 23a (quoting *Basic*, 485 U.S. at 236 (quoting *TSC Indus., Inc. v. Northway, Inc.*, 426 U.S. 438, 450 (1976)) (second alteration in original)). Instead, courts assessing materiality should engage in a "'fact-specific inquiry.'" App. 23a (quoting *Basic*, 485 U.S. at 240).[6]

Thus, a correct analysis of materiality on the facts alleged here asks whether "'a reasonable shareholder would consider it important'" that large numbers of Zicam users had lost their sense of smell – *i.e.*, whether that fact "'would have been viewed by the reasonable investor as having significantly altered the "total mix" of information made available.'" *Basic*, 485 U.S. at 231-32 (quoting *TSC Indus.*, 426 U.S. at 449). The Ninth Circuit answered this question in the affirmative, compiling the myriad undisclosed facts about a Zicam-anosmia link that a reasonable investor likely would have considered significant. App. 24a-26a.

Despite the foregoing, petitioners misread *Basic* and suggest that this Court erected its bright-line exclusion only in *that* case. Pet. 14 ("But the Court in *Basic* rejected the bright-line rule *proposed in that case* because it was based on policy considerations" not tied to the significance of the information for investors.) (emphasis added). That is not what this Court said, however; it explained that "*[a]ny* approach that designates a single fact or occurrence as always determinative of an inherently fact-specific finding such as materiality, must necessarily be over- or underinclusive." *Basic*, 485 U.S. at 236 (emphasis added).

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[6] Indeed, "'[d]etermining materiality in securities fraud cases "should ordinarily be left to the trier of fact."'" App. 23a (citations omitted); *see also Asher v. Baxter Int'l Inc.*, 377 F.3d 727, 735 (7th Cir. 2004) (Easterbrook, J.) ("inappropriate to entertain" defendants' immateriality argument at the pleading stage).

That incorrect approach is precisely the one the district court took with its singular focus on the concept of "statistical significance," and the Ninth Circuit correctly rejected it. The Ninth Circuit's holding faithfully follows *Basic*, making review here unnecessary.

B. Petitioners' Supposed Circuit Split Concerning the Relationship Between Materiality and Statistical Significance Is Illusory

Positioning the Ninth Circuit's rejection of requiring statistical significance for materiality as an outlier holding, petitioners claim that three other circuits "have adopted" what they call a "statistical significance standard": the First Circuit in *New Jersey Carpenters Pension & Annuity Funds v. Biogen IDEC Inc.*, 537 F.3d 35 (1st Cir. 2008); the Second Circuit in the *Carter-Wallace* cases; and the Third Circuit in *Oran v. Stafford*, 226 F.3d 275 (3d Cir. 2000). Pet. 7-10. Upon closer scrutiny, however, the "standard" applied by those circuits does nothing to undermine the Ninth Circuit's rejection of a bright-line approach as applied to materiality.

In *Biogen*, when the First Circuit mentioned the notion of "statistical significance," it was not addressing it in the context of materiality like the Ninth Circuit had; rather, it was conducting a case-specific, fact-specific *scienter* inquiry. *See Biogen*, 537 F.3d at 47 ("Even if plaintiffs met the standard of showing a *material* misrepresentation or omission, *as we assume arguendo they did*, they must still allege facts giving rise to a 'strong inference' of scienter.") (emphasis added). The Ninth Circuit's scienter inquiry here, in contrast, followed *Tellabs*'s totality-of-the-circumstances approach, and so did not even address "statistical significance" in that portion of its opinion. *See infra* §II.D.; *see* App. 26a-34a. *Biogen* thus is, simply and

starkly, inapposite to the Ninth Circuit's materiality holding that petitioners challenge.

Similarly, in *Carter-Wallace*, the sole issue again was scienter; the panel noted that the defendants had *conceded* all of the other elements of a securities-fraud claim. *See In re Carter-Wallace Sec. Litig.* ("*Carter-Wallace II*"), 220 F.3d 36, 39 (2d Cir. 2000) ("For purposes of its motion [for judgment on the pleadings], Carter-Wallace has conceded *all of the elements* of the appellants' claim *except scienter*.") (emphasis added). Thus, with materiality conceded, there was no need for the Second Circuit to hold that "statistical significance" was a prerequisite to finding materiality.

Notably, petitioners omit that the Second Circuit subscribes to the same view as the Ninth Circuit when it comes to materiality: that a "bright-line" materiality standard is at odds with this Court's teachings in *Basic*. *See, e.g.*, *Ganino v. Citizens Utils. Co.*, 228 F.3d 154, 162 (2d Cir. 2000) (agreeing with plaintiffs and the SEC as *amicus curiae* that the district "court's exclusive reliance on a single numerical or percentage benchmark to determine materiality was error"). *Ganino* notes there is "ample authority" supporting that narrow view of materiality as error – and pointedly cites to *Basic*. *See id.* (citing *Basic*, 485 U.S. at 236 & n.14).

Finally, although the Third Circuit in *Oran* did discuss statistical significance in connection with materiality, *Oran*'s materiality holding turned primarily on the lack of stock-price movement there in connection with allegedly material disclosures. Because defendants' disclosure of certain (allegedly damaging) data "had no appreciable negative effect on the company's stock price" – indeed, the stock actually rose in the days following the disclosure – "this price stability *is dispositive* of the question of materiality." *Oran*, 226 F.3d at 283 (emphasis added).

Oran went on to discuss "statistical significance" in connection with the materiality of other undisclosed data and adverse-reaction reports, but its reliance upon *Carter-Wallace* for the point shows that it – like petitioners here – misunderstood *Carter-Wallace* as constructing a statistical-significance/materiality regime.[7] The Third Circuit has since confirmed that *Oran*'s "materiality" holding is a stock-price-movement inquiry. *See In re Merck & Co. Sec. Litig.*, 432 F.3d 261, 269 (3d Cir. 2005) (describing the "*Oran-Burlington* standard" as one in which the materiality of disclosed information may be measured *post hoc* by looking to stock-price movement in the period immediately following disclosure).

Plainly, the Ninth Circuit did not reject the idea of "statistical significance" *generally*, as petitioners would have this Court believe. Rather, the *Matrixx* panel simply held that the district court's substitution of a singular benchmark in place of the nuanced materiality inquiry described in *Basic* was reversible error. *See* App. 23a ("We conclude, however, that the district court erred in relying on the statistical significance standard to conclude that Appellants failed adequately to allege materiality."). That holding, far from conflicting with other circuits' view of materiality, actually comports with them. *See, e.g.*, *Ganino*, 228 F.3d at 162 ("exclusive reliance on a single numerical or percentage benchmark to determine materiality was error"); *Martinez v. Schlumberger, Ltd.*,

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[7] Moreover, *Oran*'s conclusion that withheld data and adverse-reaction reports could not – *as a matter of law, no less* – be material to investors unless deemed statistically significant (226 F.3d at 284) directly contradicts this Court's holding in *Basic*. *Cf. Basic*, 485 U.S. at 236 ("Any approach that designates a single fact or occurrence as always determinative of an inherently fact-specific finding such as materiality, must necessarily be over- or underinclusive."). Thus, it is *Oran* that appears to be the outlier on materiality, not *Matrixx*.

338 F.3d 407, 428 (5th Cir. 2003) ("*Basic* suggests that we are not to rely on a bright-line test to determine whether a company's alleged misrepresentations are material."); *Kurz v. Philadelphia Elec. Co.*, 994 F.2d 136, 139 (3d Cir. 1993) (citing *Basic*, and rejecting bright-line materiality rule suggested by defendant even though it "would be easier to administer"); *Rowe v. Maremont Corp.*, 850 F.2d 1226, 1234 (7th Cir. 1988) ("Materiality is necessarily a fact-specific inquiry, so 'any approach that designates a single fact or occurrence determinative of . . . materiality must necessarily be over- or underinclusive.'") (quoting *Basic*, 485 U.S. at 236).

Petitioners' circuit split is illusory.

C. The Fact-Bound Nature of the Panel's Materiality Holding Further Counsels Against Review

Review by this Court is also unwarranted because of the fact-bound nature of the decision below. In considering this premise, respondents respectfully suggest, it is important to keep in mind what the panel's statistical-significance holding is about – and more importantly, what it is *not* about.

At its core, the Ninth Circuit's decision concerned the materiality of information that petitioners failed to disclose to investors even while speaking constantly to the market about Zicam. That specific information – the horrific, life-altering injuries striking a number of Zicam users immediately after they used the product – came into Matrixx's executive suites through a variety of channels: otolaryngology researchers, consumer complaints, and personal-injury lawsuits. And yet during the Class Period petitioners misled investors, insisting that Zicam's safety and efficacy had been well established in clinical trials, and denying any asserted link between Zicam and

anosmia as "*completely unfounded and misleading.*" App. 10a (emphasis added). Despite having been sued in October 2003 for Zicam-induced anosmia (App. 25a), Matrixx's November 2003 SEC filings omitted that material fact – warning only that: "We may incur significant costs resulting from product liability claims." App. 8a. Before the end of the Class Period, three similar lawsuits had been filed against petitioners by seven additional plaintiffs. App. 25a-26a. After the Class Period, petitioners *admitted* that there was "*insufficient evidence at this time to determine if [Zicam]*, when used as recommended, *affects a person's ability to smell.*" ER68:¶46; App. 14a-15a (emphasis added). And yet during the Class Period petitioners had reassured investors that the "safety and efficacy" of Zicam had already been "well established" in clinical trials. App. 11a, 14a.

Given the stark contrast between what petitioners knew during the Class Period, and what they told the market, the Ninth Circuit correctly decided that the Complaint's allegations comprised the very sort of facts that would be material to Matrixx investors. App. 24a-26a.

Petitioners mischaracterize the lawsuit as one primarily involving so-called "adverse event reports" – a phrase they repeat 5 times in the Question Presented, and 12 more times in their Introduction alone. Petitioners' focus on the unique animals that are adverse-event reports allows them to bootstrap the caselaw discussing those specific reports with their attack on the panel's materiality holding. Yet official adverse-event reports may often be immaterial – compared to the pointed complaints about Zicam-induced anosmia that petitioners received. Under FDA regulations, an "adverse drug experience" is defined broadly to include "*[a]ny* adverse event associated with the use of a drug in humans, *whether or not con-*

sidered drug related." 21 C.F.R. §314.80(a) (emphasis added). Thus, a drug company will receive adverse-event reports "regardless of whether or not the illness had anything to do with" the company's product. *Carter Wallace II*, 220 F.3d at 41; *accord id.* ("Some adverse events may be expected to occur randomly, especially with a drug designed to treat people that are already ill.").

In contrast to that randomness, however, the complaints made to petitioners here concerned a singular, dramatic reaction – the user's loss of sense of smell following Zicam's application into the nose – that complainants and medical researchers each attributed specifically to Zicam. The broad randomness of typical adverse-event reports is absent; these were specific, *identical* complaints brought to petitioners' attention. On those unique facts, the Ninth Circuit correctly ruled that reasonable investors would have wanted to know the undisclosed information before making the decision to buy Matrixx securities.

This Court's review is also unwarranted because the overall concept of "statistical significance" urged by petitioners is a poor proxy for Rule 10b-5 "materiality." While the latter concept concerns the importance a reasonable investor would affix to undisclosed or misstated information (*Basic*, 485 U.S. at 232), the former is "a technical term that concerns only whether an observed relationship is real or is the product of chance variation or the effect of an intervening variable." Melvin Aron Eisenberg, *Bad Arguments in Corporate Law*, 78 Geo. L.J. 1551, 1555 (1990). In other words, statistical significance "means that an observed difference cannot be attributed to chance alone, that something besides random error is afoot." Jack F. Williams, *Distrust: The Rhetoric and Reality of Means-Testing*, 7 Am. Bankr. Inst. L. Rev. 105, 131 n.105 (1999).

Notably, for purposes of a civil suit such as this, statistically significant differences "may or may not be *practically or legally significant.*" Williams, *supra*, 7 Am. Bankr. Inst. L. Rev. at 131 n.105 (emphasis in original); *see also* Richard Lempert, Symposium on Law and Economics: *Statistics in the Courtroom: Building on Rubinfeld*, 85 Colum. L. Rev. 1098, 1099 (1985) ("Statistical significance and substantive significance do not necessarily coincide; the likelihood of a statistically significant relationship varies both with sample size and the appropriateness of the statistical procedures."). The standard of proof in this civil action is a preponderance of the evidence, and "[w]hether a correlation between a cause and a group of effects is more likely than not – particularly in a legal sense – is a different question from that answered by tests of statistical significance, which often distinguish narrow differences in degree of probability."[8] Plainly, the requisite *materiality* of the undisclosed Zicam injuries known to petitioners need not necessarily coincide with the *statistical significance* of that same information – and the Ninth Circuit correctly recognized this.

Finally, this Court's review is unwarranted because the alleged anosmia reports linked to Zicam satisfy even the statistical-significance yardstick that the *Carter-Wallace* panels utilized.

Carter-Wallace was a securities-fraud action involving a pharmaceutical company and its epilepsy drug Felbatol. *Carter-Wallace II*, 220 F.3d 36; *In re Carter-Wallace, Inc.* ("*Carter-Wallace I*"), 150 F.3d 153 (2d Cir. 1998). Plaintiffs had alleged that the defendants' awareness of some 57 "adverse medical reports" concerning Felbatol users had triggered the company's duty to disclose those

[8] *Allen v. United States*, 588 F. Supp. 247, 417 (D. Utah 1984), *rev'd on other grounds*, 816 F.2d 1417 (10th Cir. 1987).

reports to investors. *Carter-Wallace II*, 220 F.3d at 38. The Second Circuit disagreed, explaining that most of the 57 adverse reports were *unrelated to Felbatol use*, and thus not "statistically significant." *Id.* at 41. Only 6 of the 57 reports concerned "aplastic anemia," a frequently fatal form of acquired bone marrow failure. *Id.* at 38. "The other illnesses ... *were never linked* to Felbatol." *Id.* at 41 (emphasis added). Once defendants had received 4 additional reports of aplastic anemia linked to Felbatol, however, the number of adverse incidents – a total of 10 – *had* risen to what the panel deemed a statistically significant level. *Id.* at 40-42. It was on that date, held the Second Circuit, that "the linkage was established between aplastic anemia and Felbatol." *Id.* at 42.

Under that reasoning, the facts here satisfy even the significance benchmark that petitioners demand – for the Complaint tabulates at least 23 specifically linked Zicam-anosmia complaints – more than *double* the 10 adverse events deemed significant in *Carter-Wallace*. The math is straightforward: There were the ten anosmia cases detailed in the September 2003 Jafek-Linschoten-Murrow poster presentation, of course. App. 5a-6a. But there were also many others: The "cluster" of cases observed by Dr. Hirsch since 1999, with "at least one" described to Matrixx in December 1999 (ER68:¶25); the several patients Dr. Linschoten had treated for Zicam-linked anosmia, including one patient who had also complained to Matrixx (and whose complaint had prompted petitioner Clarot's September 2002 phone call to Dr. Linschoten) (ER68:¶26; App. 5a); the "other customers" whom Clarot conceded had been complaining to Matrixx "as early as 1999" (*id.*); and the nine plaintiffs in the four product liability lawsuits filed before and during the Class Period (ER68:¶49). Even under the most-conservative tabulation of these various injured consumers, the number of Zicam-anosmia complaints communicated to Matrixx

prior to and during the Class Period adds up to at least 23.[9]

That large number of undisclosed complaints, juxtaposed with petitioners' admission in their SEC filings that just one product-liability lawsuit against Matrixx could have crippling financial and reputational effects (App. 8a-9a), shows that the truth behind petitioners' omissions and misleading denials would have been highly material to Matrixx investors. Undoubtedly those investors also would have regarded as material the fact that petitioners claimed that Zicam's safey and efficacy had been established despite not knowing if that claim was accurate. The Ninth Circuit reached the correct result.

D. The Ninth Circuit's Scienter Holding Is Perfectly Consistent with This Court's *Tellabs* Standard

Almost as an afterthought, petitioners briefly address the Ninth Circuit's scienter holding. Pet. 16-17. They advance the fact-based argument that, under this Court's *Tellabs* decision, it is they who enjoy the more-compelling inference arising out of their nondisclosure of information relating to Zicam. Pet. 16. The supposed inference

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[9] Respondents have counted only the Dr. Jafek ten, Dr. Hirsch's one, Dr. Linschoten's/Clarot's one, the nine product-liability plaintiffs, and just two Zicam users from Clarot's admission of "other customers." The number of Zicam-anosmia reports known to petitioners increases if one credits the inferences that (a) Dr. Linschoten also told Clarot of her other, "several" patients suffering from Zicam-linked anosmia, and (b) the consumers complaining directly to Matrixx since 1999 totaled more than just two individuals. And, the numbers grow larger still if one accepts the equally compelling inference that at least some of the other *288* plaintiffs who eventually filed suit against Matrixx (ER68:¶49), or the *165* Zicam-anosmia patients evaluated by Doctors Jafek and Linschoten (ER68:¶30), also complained to Matrixx beforehand.

in petitioners' favor? That they did not disclose the information because "it was medically meaningless." *Id.*

This factual assertion neither comports with the record, nor credits the entirety of the Ninth Circuit's "holistic" scienter analysis. App. 32a.

Going through the record, the Ninth Circuit pointed out myriad facts supporting a strong inference of petitioners' scienter: By the time of petitioners' October 22, 2003 press release and conference call, petitioners were aware "of at least fourteen complaints regarding Zicam and anosmia." App. 29a. When petitioners spoke about the reputational and financial risks of product-liability claims in their November 2003 Form 10-Q "in the abstract," they gave no indication that the risk may have already come to fruition (App. 30a) – *i.e.*, the filing of the *Christensen* lawsuit. By the time of petitioners' February 2, 2004 press release disclaiming any possible link between Zicam and anosmia, in truth

> a strong inference can be drawn that [petitioners] knew that the statements alleging a link between Zicam and anosmia were not "completely unfounded and misleading." [Petitioners] allegedly knew about the presentation by Jafek to the American Rhinologic Society, Clarot's conversation with Linschoten, and several lawsuits alleging that Zicam caused anosmia.

App. 31a. In addition, petitioners' statements in that same press release that Zicam's safety had been "well established" by clinical trials conflicted with allegations that

> *Clarot told Linschoten* in September 2002 *that Matrixx had not conducted any studies* and asked her to participate in studies. The references in the press release to clinical trials establishing Zicam's safety also conflict with the March 4, 2004, news report that *Matrixx did not know* if Zicam could cause anosmia

> and [had] formed a medical advisory panel to conduct studies.

Id. (emphasis added). The court also rejected the district court's (mistaken) belief that respondents had to have shown petitioners' "motive" to raise a strong inference of their scienter. App. 28a; App. 32a ("'the absence of a motive allegation is not fatal'") (quoting *Tellabs*, 551 U.S. at 325). Viewing respondents' Complaint as a whole, the scienter inference raised was "'cogent and at least as compelling' as any 'plausible nonculpable explanation[]'" for petitioners' conduct. App. 33a (quoting *Tellabs*, 551 U.S. at 324).

In light of the foregoing fact-specific analysis, the Ninth Circuit's scienter holding was wholly consistent with this Court's admonition to consider a complaint's "allegations holistically." *Tellabs*, 551 U.S. at 326. It also was consonant with other circuits' similar reasoning concerning defendants' public statements in the face of undisclosed, contradictory information. *See, e.g., Fla. State Bd. of Admin. v. Green Tree Fin. Corp.*, 270 F.3d 645, 665 (8th Cir. 2001) (one of the "classic fact patterns" giving rise to a strong scienter inference is that defendants made certain statements "when they knew facts or had access to information suggesting that their public statements were materially inaccurate") (collecting cases); *Helwig v. Vencor, Inc.*, 251 F.3d 540, 552 (6th Cir. 2001) (en banc) (defendants' "disregard of the most current factual information" while making statements into the market is one of the "fixed constellations of facts that courts have found probative of securities fraud").

Petitioners' attempt to disparage the undisclosed information regarding Zicam's link with anosmia as "medically meaningless," and to defend the district court's elevation of "statistical significance" to the sole scienter inquiry, necessarily fail.

Given the unique facts presented, this Court's materiality and scienter precedents, and little evidence of an actual split of authority among the circuit courts, review is unwarranted.

III. CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted,

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REPLY BRIEF

MAY 25 2010
OFFICE OF THE CLERK

No. 09-1156

IN THE

Supreme Court of the United States

MATRIXX INITIATIVES INC., ET AL.,
Petitioners,

v.

JAMES SIRACUSANO AND NECA-IBEW PENSION FUND,
Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

REPLY BRIEF FOR PETITIONERS

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REPLY BRIEF FOR PETITIONERS

The courts of appeals are squarely divided on the question whether § 10(b) of the Securities Exchange Act of 1934 requires drug companies to disclose adverse event reports that do not reflect statistically significant evidence that an adverse event may be caused by, rather than randomly associated with, use of a drug. Respondents do not deny that this question is one of recurring, national importance. Pet. 10-13.

Respondents instead oppose review on essentially three grounds. First, they contend that circuits are not in conflict over the question presented. Opp. 13-16. Their position misconstrues both the decision below and the other circuit decisions with which it conflicts.

Second, respondents argue that the case is a poor vehicle for addressing the question presented. They contend the case involves "unique" facts because petitioners received "specific, identical complaints" of the same adverse event. Opp. 18 (emphasis omitted). But *exactly the same is true* of the conflicting circuit decisions. What produced different outcomes was the legal standard applied by the circuits, not differences in the consumer complaints alleged. Respondents' further suggestion that they would prevail even under the correct legal standard is wrong. The district court found no statistical significance, and the court of appeals did not disturb that finding. Even now, respondents make no plausible claim of statistical significance.

Finally, respondents argue that the Ninth Circuit's decision is correct, which is irrelevant to whether certiorari should be granted, and wrong as

well. The statistical significance standard is faithful to *Basic Inc. v. Levinson*, 485 U.S. 224 (1988), and necessary to evaluate whether a plaintiff has stated facts that give rise to a "strong inference" of scienter as required by *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 314 (2007).

The petition should be granted.

A. The Circuits Are In Conflict

Respondents erroneously contend that the conflict described in the petition is "illusory." Opp. 13. The Ninth Circuit below squarely rejected the statistical significance standard adopted by the First, Second, and Third Circuits for analyzing securities fraud claims based on nondisclosure of adverse event reports.

1. Respondents assert that two of the circuit precedents require statistical significance only with respect to scienter, and that the decision below is limited to materiality. Opp. 13-14 (citing *New Jersey Carpenters Pension & Annuity Funds v. Biogen IDEC Inc.*, 537 F.3d 35 (1st Cir. 2008); *In re Carter-Wallace, Inc. Sec. Litig.*, 220 F.3d 36 (2d Cir. 2000) (*Carter-Wallace II*)). This is wrong in two respects.

First, the district court in this case relied on the statistical significance standard as a measure of *both* materiality and scienter, Pet. 5; Pet. App. 45a, 54a, and the Ninth Circuit reversed the district court's dismissal on both counts, Pet. App. 34a. The decision below thus conflicts directly with the holdings in the First and Second Circuits that statistical significance is necessary to establish scienter.

Second, contrary to respondents' submission, the Second Circuit clearly requires statistical signifi-

cance *for materiality*. In the *first Carter-Wallace* decision—the seminal decision adopting the statistical significance standard—the Second Circuit expressly applied the standard to the materiality element: "The [positive] statements in Carter-Wallace's Form 10-K and its 'Report to Shareholders' did not become *materially misleading* until Carter-Wallace had information that [the drug] had caused a statistically significant number of deaths." *In re Carter-Wallace, Inc. Securities Litigation*, 150 F.3d 153, 157 (2d Cir. 1998) (emphasis added). Multiple subsequent Second Circuit decisions have applied *Carter-Wallace I* to require statistical significance for materiality. Pet. 7-8 (citing cases). Respondents inexplicably ignore *Carter-Wallace I* and its progeny.

Respondents instead discuss only the *second* decision in *Carter-Wallace*, which they say was limited to scienter. Respondents misconstrue the decision. *Carter-Wallace II* first confirms the *materiality* analysis of *Carter-Wallace I*, reiterating the prior decision's holding that a company's positive "financial statements [are] not materially misleading" unless there is a statistically significant link between the product and reported adverse events. 220 F.3d at 41. *Carter-Wallace II* then simply *extends* the statistical significance already required for materiality to scienter as well. *Id.* at 39. As the decision explains, "awareness of medical reports that could . . . be[] random cannot lead to the conclusion that [a company] was reckless" in promoting a product. *Id.* at 42 (quotation omitted).

The Second Circuit's decision in *Ganino v. Citizens Utilities Co.*, 228 F.3d 154 (2d Cir. 2000), does not, as respondents suggest, negate the materiality rulings in the *Carter-Wallace* decisions. *Ganino*

postdates those decisions, so it could not overrule them even if it were to the contrary. *See United States v. Wilkerson*, 361 F.3d 717, 732 (2d Cir. 2004) (panel cannot overrule prior panel ruling). But *Ganino* plainly is *not* to the contrary: the court there *did not even consider statistical significance.*[1] Its irrelevance is confirmed by subsequent Second Circuit decisions affirming the dismissal, on materiality grounds, of cases in which plaintiffs failed to allege statistically significant adverse event reports. Pet. 7-8. The *Carter-Wallace* rule requiring statistical significance clearly continues to control in the Second Circuit—in direct conflict with the Ninth Circuit's decision in this case.[2]

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[1] The issue in *Ganino* was whether the failure to disclose the source of certain income was immaterial as a matter of law where that income was only 1.7% of relevant revenues, and thus arguably within the "standard practice in corporate America" not to disclose a "charge or event" unless it is likely to "affect [the] company's earnings, positively or negatively, by 3% to 10%." 228 F.3d at 161. The court of appeals reaffirmed that "[a]n omitted fact may be immaterial if the information is trivial," but refused to permit materiality under those circumstances to turn on "[m]agnitude by itself, without regard to the nature of the [undisclosed] item." *Id.* at 162 (quotation omitted). The proper approach, the court explained, was to consider what the omitted figure meant. For example, the court could consider whether a misstated figure "masks a change in earnings or other trends," or "hides a failure to meet analysts' consensus expectations for the enterprise." *Id.* at 163 (quotation omitted). *Ganino* is thus entirely consistent with the statistical significance standard, which does not turn on a raw number of adverse event reports ("magnitude") but rather considers what those reports mean—whether they suggest a causal connection between product and event or reflect only random chance.

[2] Respondents also cite decisions from the Third, Fifth, and Seventh Circuits that ostensibly "comport[] with" the Ninth Circuit's rejection of the statistical significance standard. Opp.

2. Though respondents err in describing the Second Circuit's statistical significance requirement as limited to scienter, they correctly concede that the Third Circuit's decision in *Oran v. Stafford*, 226 F.3d 275, 283-84 (3d Cir. 2000), addressed statistical significance "in connection with materiality." Opp. 14. Respondents nevertheless contend that *Oran* can be ignored because then-Judge Alito's opinion "misunderstood" *Carter-Wallace*. Opp. 15. But respondents' disagreement with *Oran*'s materiality holding does not change the fact that *Oran* is binding in the Third Circuit and squarely conflicts with the decision below. In any event, as just shown, *Oran* accurately reads *Carter-Wallace I* as adopting a statistical significance requirement for purposes of materiality. The Third Circuit thus made no error in expressly following *Carter-Wallace* to hold that "'drug companies need not disclose isolated reports of illnesses suffered by users of their drugs until those reports provide statistically significant evidence that the ill effects may be caused by—rather than randomly associated with—use of the drugs,'" because reports that are not statistically significant are not material. 226 F.3d at 284 (quoting *Carter-Wallace I*, 150 F.3d at 157).

There also is no merit to respondents' suggestion that "*Oran*'s materiality holding turned primarily on the lack of stock-price movement there in connection with allegedly material disclosures." Opp. 14. The claims in *Oran* were premised on multiple omissions, and the court rested its holding on stock price only

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15-16. Those cases, however, do not even consider the statistical significance standard, and general references to *Basic*'s materiality rule do not constitute rejection of that standard, which is perfectly consistent with *Basic*, as explained *infra* at 9-11.

with respect to what was known as "the Mayo data." 226 F.3d at 283. The court in no way relied on stock price in evaluating the "European data and the adverse reaction reports." *Id.* at 284. The court held that information immaterial solely because it was not statistically significant. *See id.* at 283-84. That holding, like the holding in *Carter-Wallace* that it followed, cannot be reconciled with the Ninth Circuit's decision below.[3]

B. This Case Is A Good Vehicle For Review

Respondents cannot deny that the Ninth Circuit expressly rejected "the statistical significance standard used by the Second Circuit in *In re Carter-Wallace*" and held without qualification that "reliance on the statistical significance standard to conclude that [respondents] failed to establish materiality [was] inconsistent with the Supreme Court's rejection of bright-line rules." Pet. App. 23a, 34a. And respondents affirmatively concede that the validity of the statistical significance standard is squarely presented by this case. Opp. i (stating that a question presented by this case is whether the Ninth Circuit "correctly held that the district court's reliance upon a singular 'statistical significance' standard in order to assess . . . materiality" was in error); *id.* at 11 (observing that, "[f]aced with a district-court decision requiring that the 'materiality' element of a securities-fraud claim be supported by 'statistically

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[3] Even assuming that *Oran*'s "primary" holding turned on stock price, and the court's adoption of the statistical significance standard were an alternative holding, that holding would still be binding, and the conflict would remain. *See United States ex rel. Caruso v. Zelinsky*, 689 F.2d 435, 440 (3d Cir. 1982) ("an alternate holding has the same force as a single holding; it is binding precedent").

significant' information, the Ninth Circuit . . . reject[ed] that bright-line approach").

Respondents nevertheless contend that certiorari is inappropriate because the decision below is limited to "unique" facts. Opp. 17-18. It is not. Respondents assert that the adverse event reports "concerned a singular, dramatic reaction" and thus presented "specific, identical complaints" that differ from the "broad randomness of typical adverse-event reports" in other cases. Opp. 17-18 (emphasis omitted). In fact, *every other case* applying the statistical significance standard has involved exactly the same kind of "specific, identical complaints" of a single dramatic reaction—indeed, of life-threatening conditions far more severe than anosmia. In *Carter-Wallace*, the company received "information . . . indicating that [its drug] caused, in some patients, a fatal form of acquired bone-marrow failure known as aplastic anemia." *Carter-Wallace I*, 150 F.3d at 155. In *Oran*, the company "knew of at least 31 cases of heart valve abnormalities in European diet-pill users." 226 F.3d at 279. In *New Jersey Carpenters*, the cited clinical trials involved four deaths from opportunistic infections. 537 F.3d at 50.

The facts of this case thus fall well within the norm for statistical significance cases. Indeed, the question of statistical significance arises in these cases precisely *because* there are multiple reports of the same adverse event allegedly associated with use of a certain drug. The question in such cases is whether those reports suggest that "ill effects may be caused by—rather than randomly associated with—use of the drugs and are sufficiently serious and frequent to affect future earnings." *Carter-Wallace I*, 150 F.3d at 157. This case thus poses ex-

actly the same problem presented by other statistical significance cases—the only difference is the one difference that matters: the Ninth Circuit applied a different legal standard and thereby reached the opposite result.

Respondents also suggest that review should be denied because their complaint would survive dismissal even under the legal standard applied in other circuits. Not so: the complaint did not allege statistical significance; the district court concluded that the incident reports were not statistically significant; and respondents did not amend their complaint to allege statistical significance, even after the district court offered them the opportunity to do so (Pet. App. 53a-54a). Nor did the Ninth Circuit suggest in any way that the complaint could survive the statistical significance standard—to the contrary, the court resurrected the complaint only by rejecting the statistical significance standard as a matter of law. The validity of that legal ruling is squarely at issue here.

In any event, respondents' complaint clearly would not pass muster under the correct standard. Respondents emphasize that what they count to be 23 adverse event reports are "more than *double* the 10 adverse events deemed significant in *Carter-Wallace*." Opp. 20.[4] As respondents' opposition itself

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[4] Respondents miscalculate the number of relevant reports. The complaint does not, as they assert, "tabulate[]" the reports received during the class period. Opp. 23. In addition, the complaint does not allege that the nine plaintiffs in Zicam-related lawsuits were additional complainants, rather than a subset of the 12 individuals whose events had already been reported to Matrixx. Pet. 4 & n.1. In any event, the precise number of reports is for present purposes irrelevant—

acknowledges, however, statistical significance is not measured by the raw number of adverse event reports a company receives. The number of reports must be evaluated in light of various other factors, including the sample size from which the reports are taken. Opp. 19 (citing article recognizing importance of "sample size" for statistical significance). In *Carter-Wallace I*, the drug company itself conceded based on a study conducted in coordination with the FDA that 10 adverse incident reports of its prescription drug provided statistically significant evidence of a causal connection where the company received those reports in a seven-month period, and the last four complaints were received in one month. 150 F.3d at 154-55, 157.

In this case, by contrast, respondents point to only a small number of complaints received over the course of five years for an over-the-counter product for which millions of units have been sold. *See generally* Matrixx Initiatives, Inc., Form 10-K Annual Report (Mar. 28, 2003) (Zicam Cold Remedy accounted for more than 70% of 2002 net sales of $23.5 million). There can be no plausible allegation that the minuscule number of reports received, compared to millions of products sold over five years, was statistically significant.

C. The Decision Below Is Incorrect

Respondents finally contend that the Ninth Circuit's decision is correct. Those merits arguments are just that—merits arguments, not reasons to deny certiorari. And they are wrong in any event.

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respondents have failed to allege statistically significant reports by anyone's calculation. *Id.*

1. The statistical significance standard is not contrary to *Basic*. Opp. 11-13. *Basic* holds that information is not material unless there is "a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available." 485 U.S. at 231-32. Application of the statistical significance standard not only comports with *Basic*, it is actually compelled by *Basic*'s rule: one cannot determine "whether a reasonable shareholder would consider it important" that a number of "Zicam users had lost their sense of smell" (Opp. 12 (quotation omitted)) without knowing whether that number suggests a "causal connection between [drug] and [event]" or rather a "random and statistically insignificant" response that "may be expected to occur" with any drug, particularly "a drug designed to treat people that are already ill." *Carter-Wallace II*, 220 F.3d at 40, 41; *see Jackvony v. RIHT Fin. Corp.*, 873 F.2d 411, 415 (1st Cir. 1989) (Breyer, J.) (citing *Basic* in holding that internal discussion regarding merger feeler preceding any negotiations is categorically non-material because "[a]ny reasonably sophisticated investor in securities buying shares in a large corporation would expect that, from time to time, other corporations might express an interest in buying, or that the large corporation's directors might discuss what it should do if it obtains such offers").

The statistical significance inquiry thus is not the type of "bright-line" rule the Court declined to adopt in *Basic*. In *Basic*, the Court rejected a rule that made materiality turn on the existence of a "single fact or occurrence" that was not tied to "the significance of [that] information upon the investor's deci-

sion." 485 U.S. at 234, 236. The statistical significance standard, by contrast, is directly tied to the significance of the information to an investor's decision. And it operates to determine whether multiple potentially relevant facts—i.e., adverse event reports—could possibly have sufficient clinical meaning to be significant to a reasonable investor.

2. Application of a statistical significance standard is also necessary to satisfy the requirement that plaintiffs plead with particularly facts giving rise to a "strong inference" of scienter. 15 U.S.C. § 78u-4(b)(2). Where adverse event reports are not statistically significant, the inference that nondisclosure of such reports was motivated by fraudulent intent simply is not "at least as compelling as any opposing inference of nonfraudulent intent." *Tellabs*, 551 U.S. at 314. The much more compelling inference is that the reports were not disclosed simply because no appropriate medical or scientific inferences could be drawn from them. Pet. 16-17.

Respondents insist that an inference of medical non-significance does not "comport[] with the record" of this case. Opp. 22. As explained above, however, nothing in the record suggests that the non-disclosed reports reflected any statistically valid inference that Zicam use caused the reported events. And contrary to the Ninth Circuit's decision, "[w]ithholding reports of adverse effects" cannot reasonably be deemed "an extreme departure from the standards of ordinary care" (Pet. App. 33a (quotation omitted)) where those reports do not establish any statistically significant relationship between product and adverse event. *See Carter-Wallace II*, 220 F.3d at 42 ("Carter-Wallace's awareness of medical reports that could have been random cannot lead to the conclu-

sion that Carter-Wallace was reckless in permitting the advertisements to continue."). In short, it is impossible to find a strong inference of scienter on the basis of adverse event reports that are statistically meaningless. The Ninth Circuit's decision to the contrary is wrong.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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May 25, 2010

JOINT APPENDIX

Supreme Court, U.S.
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MATRIXX INITIATIVES INC., ET AL.,
Petitioners,

v.

JAMES SIRACUSANO AND NECA-IBEW PENSION FUND,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

JOINT APPENDIX

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APPENDIX A

U.S. District Court
DISTRICT OF ARIZONA (Phoenix Division)
CIVIL DOCKET FOR CASE #: 2:04-cv-00886-MHM

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Assigned to: Judge Mary H Murguia
Demand: $0
Case in other court: Ninth Circuit, 06-15677
Cause: 15:78m(a) Securities Exchange Act

Date Filed: 04/27/2004
Date Terminated: 03/08/2006
Jury Demand: Plaintiff
Nature of Suit: 850 Securities/Commodities
Jurisdiction: Federal Question

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V.

Defendant

Timothy L Clarot

Date Filed	#	Docket Text
04/27/2004	1	COMPLAINT FILED (LSP) (Entered: 04/29/2004)
06/10/2004	2	ORDERED that pla Stanley Sved show cause for failure to comply with Local Rule 1.2(e) ; show cause hearing set for 1:30 7/12/04 for Stanley Sved before Judge

		Stephen M. McNamee (cc: all counsel/AL) (MAP) (Entered: 06/10/2004)
06/15/2004	3	Party elects assignment of case to district judge ; mag election form ddl satisfied 6/15/04 ; show cause hearing ddl satisfied 6/15/04 (MAP) (Entered: 06/16/2004)
06/16/2004	4	MINUTE ORDER that pursuant to Local Rule 1.2(e), a request has been received for a random reassignment of this case to a District Judge FURTHER ORDERED Case reassigned by random draw to Judge Mary H. Murguia All further papers/pleadings should now list the following COMPLETE case number: CIV-04-886-PHX-MHM FURTHER ORDERED that the Order to Show Cause hearing scheduled for 7/12/04 is hereby vacated (cc: all counsel/DKD/MHM) [4-2] (MAP) (Entered: 06/16/2004)
06/28/2004	5	STIPULATION to extend time for Dfts to answer complaint [1-1] by pla, dfts [5-1] (MAP) (Entered: 06/29/2004)
07/02/2004	6	NOTICE OF ATTORNEY APPEARANCE/ASSOCIATION for pla Stanley Sved by attorney(s) Steven G Schulman, Peter E Seidman, Andrei V Rado, Marc S

		Henzel, Christopher A Seeger, and David R Buchanan (KMG) (Entered: 07/08/2004)
07/12/2004	7	MOTION to consolidate cases with CV04-1012PHX-SMM by pla Stanley Sved (of NECA-IBEW Pension Fund) [7-1] , and appointment as lead plaintiff by pla Stanley Sved (of NECA-IBEW Pension Fund) [7-2] , and approval of selection of lead and liaison counsel by pla Stanley Sved (of NECA-IBEW Pension Fund) [7-3] (LSP) Modified on 07/15/2004 (Entered: 07/15/2004)
07/12/2004	8	MEMORANDUM IN SUPPORT by pla Stanley Sved of motion (of NECA-IBEW Fund) to consolidate cases with CV04-1012PHX-SMM by pla Stanley Sved [7-1], motion appointment as lead plaintiff by pla Stanley Sved [7-2], motion approval of selection of lead and liaison counsel by pla Stanley Sved [7-3] (LSP) (Entered: 07/15/2004)
07/12/2004	9	DECLARATION of Andrew S. Friedman re motion (of NECA-IBEW Fund) to consolidate cases with CV04-1012PHX-SMM by pla Stanley Sved [7-1] re motion appointment as lead plaintiff by pla Stanley [7-2], re motion approval of selection of lead and liaison counsel by pla Stanley Sved [7-3] by pla Stanley Sved

		(LSP) (Entered: 07/15/2004)
07/12/2004	10	MOTION of Jeffrey E. Kuhler, Stanley Sved, W.K. Hughey and Alex Costanzo to consolidate cases, CV 04-1212-PHX-SMM by pla Stanley Sved [10-1] , and to be appointed lead Plaintiff by pla Stanley Sved [10-2] , and for approval of their selection of lead and liaison counsel by pla Sved [10-3] (LSP) Modified on 07/15/2004 (Entered: 07/15/2004)
07/12/2004	11	MEMORANDUM of Law IN SUPPORT by pla Stanley Sved of motion of Jeffrey E. Kuhler, Stanley Sved, W.K. Hughey and Alex Costanzo to consolidate cases, CV 04-1212-PHX-SMM by pla Stanley Sved [10-1] [10- 1], motion to be appointed lead Plaintiff by pla Stanley Sved [10-2], motion for approval of their selection of lead and liaison counsel by pla Sved [10-3] (LSP) Modified on 07/15/2004 (Entered: 07/15/2004)
07/12/2004	12	DECLARATION of Andrew S. Friedman in support motion of Jeffrey E. Kuhler, Stanley Sved, W.K. Hughey and Alex Costanzo to consolidate cases, CV 04-1212-PHX-SMM by pla Stanley Sved [10-1], re motion to be appointed lead Plaintiff by pla Stanley Sved [10-2], re motion for approval of their selection of lead and liaison

		counsel by pla Sved [10-3] by pla Stanley Sved (LSP) Modified on 07/15/2004 (Entered: 07/15/2004)
07/20/2004	13	MOTION for admission pro hac vice as to Steven Schulman, atty for pla Stanley Sved [13-1] (DMT) (Entered: 07/21/2004)
07/21/2004	14	ORDER by Judge Mary H. Murguia granting stipulation to extend time for Dfts to answer complaint 1 by pla, dfts 5 FURTHER ORDERED Dfts shall have 45 days from the filing of Pla"s first amended complaint to file a responsive pleading; Pla shall have 45 days from the filing of any responsive pleading to oppose such pleading; and Dft shall have 30 days from the filing of any opposition to their responsive pleading to file their reply (cc: all counsel) (MAP) (Entered: 07/21/2004)
07/23/2004		Pro Hac Vice $25 Fee Paid as to Steven G Schulman (BAS) (Entered: 07/23/2004)
07/26/2004	16	RESPONSE (OPPOSITION) by dfts to motions for approval of their selection of lead and liaison counsel by pla Sved [10-3], motion approval of selection of lead and liaison counsel by pla Stanley Sved (of NECA-IBEW Pension Fund) [7-3] (MAP) (Entered: 07/27/2004)

07/26/2004	18	MOTION for admission pro hac vice as to Marc S. Henzel, atty for pla Stanley Sved [18-1] (LSP) (Entered: 07/28/2004)
07/27/2004		Pro Hac Vice $25 Fee Paid as to Marc S Henzel (BAS) (Entered: 07/27/2004)
07/27/2004	15	ORDER by Judge Mary H. Murguia granting motion for admission pro hac vice as to Steven Schulman, atty for pla Stanley Sved [13-1] (cc: all counsel) re: order filed [15-1] (DMT) (Entered: 07/27/2004)
07/27/2004	17	MOTION for Oral Argument re Motion for Consolidation, Appointment as Lead Plaintiff and for Approval of Selection of Lead and Liaison Counsel by pla Stanley Sved [17-1] (MAP) (Entered: 07/28/2004)
07/29/2004	19	MEMORANDUM (response) IN FURTHER SUPPORT by pla of motion of Jeffrey E. Kuhler, Stanley Sved, W.K. Hughey and Alex Costanzo to consolidate cases, CV 04-1212-PHX-SMM by pla Stanley Sved [10-1] motion to be appointed lead Plaintiff by pla Stanley Sved [10-2] [10-2], motion for approval of their selection of lead and liaison counsel by pla Sved [10-3] [10-3] (DMT) Modified on 08/02/2004 (Entered: 08/02/2004)

07/29/2004	20	MEMORANDUM IN FURTHER SUPPORT by pla of motion to consolidate cases with CV04-1012PHX-SMM by pla Stanley Sved (of NECA-IBEW Pension Fund) [7-1] [7-1], motion appointment as lead plaintiff by pla Stanley Sved (of NECA-IBEW Pension Fund) [7-2] [7-2], motion approval of selection of lead and liaison counsel by pla Stanley Sved (of NECA-IBEW Pension Fund) [7-3] [7-3] (DMT) (Entered: 08/02/2004)
07/30/2004	21	MOTION to substitute attorney D Rosenbaum and M Beyers replacing J Condo, by dft Matrixx Initiatives, dft Carl J Johnson, dft William J Hemelt [21-1] (DMT) (Entered: 08/02/2004)
08/02/2004	22	ORDER by Judge Mary H. Murguia granting motion for admission pro hac vice as to Marc S. Henzel, atty for pla Stanley Sved [18-1] (cc: all counsel) (DMT) (Entered: 08/02/2004)
08/05/2004	23	ORDER by Judge Mary H. Murguia granting motion to substitute attorney D Rosenbaum and M Beyers replacing J Condo, by dft Matrixx Initiatives, dft Carl J Johnson, dft William J Hemelt [21-1]; terminating attorney James R Condo for William Hemelt, attorney James R Condo for Carl J Johnson, attorney

		James R Condo for Matrixx Initiatives and substituting attorneys David B Rosenbaum and Maureen Beyers ; Michael G Yoder and Amy J Longo of the firm O"Melveny & Meyers LLP remain as co-counsel for dfts (cc: all counsel) (LAD) (Entered: 08/05/2004)
08/05/2004	24	MEMORANDUM IN FURTHER SUPPORT by pla Stanley Sved of motion to consolidate cases with CV04-1012PHX-SMM by pla Stanley Sved (of NECA-IBEW Pension Fund) [7-1] [7-1], motion appointment as lead plaintiff by pla Stanley Sved (of NECA-IBEW Pension Fund) [7-2] [7-2], motion approval of selection of lead and liaison counsel by pla Stanley Sved (of NECA-IBEW Pension Fund) [7-3] [7-3] (former emp) (Entered: 08/09/2004)
08/09/2004		Pro Hac Vice $25 Fee Paid as to Andrei V Rado (BAS) (Entered: 08/09/2004)
08/09/2004	25	MEMORANDUM IN SUPPORT by pla Stanley Sved of motion approval of selection of lead and liaison counsel by pla Stanley Sved (of NECA-IBEW Pension Fund) [7-3], motion appointment as lead plaintiff by pla Stanley Sved (of NECA-IBEW Pension Fund) [7-2], motion to consolidate cases with CV04-1012PHX-SMM

		by pla Stanley Sved (of NECA-IBEW Pension Fund) [7-1] (LSP) (Entered: 08/11/2004)
08/09/2004	26	MOTION for admission pro hac vice as to Andrei V. Rado, atty for pla Stanley Sved [26-1] (LSP) (Entered: 08/11/2004)
08/09/2004	27	REPLY by pla Stanley Sved to response to motion for approval of their selection of lead and liaison counsel by pla Sved [10-3], motion to be appointed lead Plaintiff by pla Stanley Sved [10-2], motion of Jeffrey E. Kuhler, Stanley Sved, W.K. Hughey and Alex Costanzo to consolidate cases, CV 04-1212-PHX-SMM by pla Stanley Sved [10-1] (LSP) (Entered: 08/11/2004)
08/11/2004	28	NOTICE by pla Stanley Sved of Change of Atty Firm Name to Lerach Coughlin Stoia Geller Rudman & Robbins (MAP) (Entered: 08/13/2004)
08/13/2004	30	MOTION for admission pro hac vice as to Christopher A. Seeger, atty for pla Stanley Sved [30-1] (LSP) (Entered: 08/16/2004)
08/13/2004	31	MOTION for admission pro hac vice as to David R. Buchanan, atty for pla Stanley Sved [31-1] (LSP) (Entered: 08/16/2004)
08/16/2004	29	ORDER by Judge Mary H. Murguia granting motion for admission pro hac vice as to Andrei V. Rado, atty for pla

		Stanley Sved [26-1] (cc: all counsel) (LAD) (Entered: 08/16/2004)
08/17/2004		Pro Hac Vice $25 Fee Paid as to Christopher A Seeger (BAS) (Entered: 08/17/2004)
08/17/2004		Pro Hac Vice $25 Fee Paid as to David R Buchanan (BAS) (Entered: 08/17/2004)
08/23/2004	32	MOTION for hearing on competing motions by dft Matrixx Initiatives, dft Carl J Johnson, dft William J Hemelt [32-1] (LAD) (Entered: 08/24/2004)
08/25/2004	33	MOTION for admission pro hac vice as to Michael G Yoder, atty for dfts [33-1] (DMT) Modified on 08/30/2004 (Entered: 08/30/2004)
08/25/2004	34	MOTION for admission pro hac vice as to Molly J Magnuson, atty for dfts [34-1] (DMT) (Entered: 08/30/2004)
08/25/2004	35	MOTION for admission pro hac vice as to Amy J Longo, atty for dfts [35-1] (DMT) (Entered: 08/30/2004)
08/30/2004	36	ORDER by Judge Mary H. Murguia granting motion for admission pro hac vice as to Amy J Longo, atty for dfts [35-1] (cc: all counsel) (former emp) (Entered: 08/30/2004)
08/30/2004	37	ORDER by Judge Mary H. Murguia granting motion for admission pro hac vice as to Molly

		J Magnuson, atty for dfts [34-1] (cc: all counsel) (former emp) (Entered: 08/30/2004)
08/30/2004	38	ORDER by Judge Mary H. Murguia granting motion for admission pro hac vice as to Michael G Yoder, atty for dfts [33-1] (cc: all counsel) (former emp) (Entered: 08/30/2004)
08/30/2004	39	ORDER by Judge Mary H. Murguia granting motion for admission pro hac vice as to David R. Buchanan, atty for pla Stanley Sved [31-1] (cc: all counsel) (former emp) (Entered: 08/30/2004)
08/30/2004	40	ORDER by Judge Mary H. Murguia granting motion for admission pro hac vice as to Christopher A. Seeger, atty for pla Stanley Sved [30-1] (cc: all counsel) (former emp) (Entered: 08/30/2004)
08/31/2004		Pro Hac Vice $25 Fee Paid as to Amy J Longo (BAS) (Entered: 08/31/2004)
08/31/2004		Pro Hac Vice $25 Fee Paid as to Molly J Magnuson (BAS) (Entered: 08/31/2004)
08/31/2004		Pro Hac Vice $25 Fee Paid as to Michael G Yoder (BAS) (Entered: 08/31/2004)
09/08/2004	41	MINUTE ORDER: The Court ORDERS granting defendant"s motion for hearing on competing

		motions [32-1] and plaintiff"s motion for oral argument re Motion for Consolidation, Appointment as Lead Plaintiff and for Approval of Selection of Lead and Liaison Counsel pla Stanley Sved [17-1]. IT IS THEREFORE ORDERED setting counsel"s competing motions for oral argument on Monday, October 18, 2004 at 4:00 p.m. before the Honorable Mary H. Murguia. (cc: MHM, all counsel) [41-1] (KSB) (Entered: 09/08/2004)
10/04/2004	42	MOTION for admission pro hac vice as to Lori G Feldman, atty for pla Stanley Sved [42-1] (MAP) (Entered: 10/06/2004)
10/07/2004		Pro Hac Vice $25 Fee Paid as to Lori G Feldman (BAS) (Entered: 10/07/2004)
10/08/2004	43	MINUTE ORDER: Due to a conflict on the Court"s calendar, the Court ORDERS that the Motion Hearing regarding counsel"s competing motions [docs 7 and 10] currently set on October 18, 2004 be RESET to October 22, 2004 at 3:00 p.m. before the Honorable Mary H. Murguia. (cc: MHM, all counsel) [43-1] (KSB) (Entered: 10/08/2004)
10/12/2004	44	MINUTE ORDER: Due to a conflict on the Court"s calendar, the Court ORDERS that the

		Motion Hearing regarding the competing motions [docs 7 and 10] currently set on October 22, 2004 be RESET to October 27, 2004 at 2:30 p.m. before the Honorable Mary H. Murguia. (cc: MHM, all counsel) [44-1] (KSB) (Entered: 10/12/2004)
10/12/2004	45	ORDER by Judge Mary H. Murguia granting motion for admission pro hac vice as to Lori G Feldman, atty for pla Stanley Sved [42-1] (cc: all counsel) (MAP) (Entered: 10/12/2004)
10/20/2004	46	MOTION for admission pro hac vice as to Eric T. Chaffin, atty for pla Stanley Sved [46-1] (MAP) (Entered: 10/21/2004)
10/22/2004		Pro Hac Vice $25 Fee Paid as to Eric T Chaffin (BAS) (Entered: 10/22/2004)
10/26/2004	47	ORDER by Judge Mary H. Murguia granting motion for admission pro hac vice as to Eric T. Chaffin, atty for pla Stanley Sved [46-1] (cc: all counsel) (DMT) (Entered: 10/26/2004)
10/26/2004	48	MOTION (Application) of Attorney for Admission to Practice Pro Hac Vice Pursuant to Local Rule 1.5(b)(3) as to Ramzi Abadou, atty for movant NECA-IBEW [48-1] (SAT) (Entered: 10/26/2004)
10/26/2004		Pro Hac Vice $25 Fee Paid as to Ramzi Abadou (BAS) (Entered:

		10/26/2004)
10/27/2004	49	MINUTE ENTRY before Judge Mary H. Murguia. Crt Rptr: Merilyn Sanchez. Appearances: Ramzi Abadou, Stephen Weiss, Lori Feldman, Christopher Seeger, David Buchanan, and Francis Balint for the plaintiffs. David Rosenbaum, Amy Longo, and Maureen Beyers for the defendants. Also present is defendant, William Hemelt. Motions Hearing held. There being no objection, IT IS ORDERED granting the Motion to Consolidate CV 04-1012-PHX-SMM with this case [10, 7-1]. Oral argument held. IT IS FURTHER ORDERED taking under advisement the Motion to Appoint Lead Plaintiff [10,7-2] and for Approval of Their Selection of Lead Liaison Counsel [10,7-3]. The Court DIRECTS counsel to provide briefing on the conflict issue, if necessary, by November 10, 2004. [cc: MHM, docket clerk] [49-1] (KSB) Modified on 10/28/2004 (Entered: 10/28/2004)
10/29/2004	50	ORDER by Judge Mary H. Murguia granting motion (Application) of Attorney for Admission to Practice Pro Hac Vice Pursuant to Local Rule 1.5 (b)(3) as to Ramzi Abadou, atty for movant NECA-IBEW [48-1] (cc: all

		counsel) (KMG) (Entered: 10/29/2004)
11/01/2004	51	Transcript Designation and Ordering Form by dfts re Pretrial Proceedings of 10/27/04 (MAP) (Entered: 11/05/2004)
11/04/2004	52	Transcript Designation and Ordering Form by movant NECA-IBEW re Pretrial Proceedings of 10/27/04 (MAP) (Entered: 11/05/2004)
11/09/2004	53	STIPULATION re Dfts" Opposition to Motions for Lead Pla and Lead Counsel by pla, dfts (MAP) (Entered: 11/17/2004)
11/10/2004	54	POST -Hearing Submission by Kuhler Movants re conflict of interest (MAP) (Entered: 11/17/2004)
11/24/2004	55	TRANSCRIPT of motions hearing by Court Reporter: Merilyn Sanchez for the following date(s): 10/27/04 (SRB) (Entered: 11/29/2004)
12/09/2004	56	RETURN OF SERVICE EXECUTED summons/complaint (personal) upon dft William J Hemelt on 5/21/04 (MAP) (Entered: 12/13/2004)
12/09/2004	57	RETURN OF SERVICE EXECUTED summons/complaint upon William J Hemelt for dft Carl Johnson on 5/21/04 (MAP) (Entered: 12/13/2004)
12/09/2004	58	RETURN OF SERVICE

		EXECUTED summons/complaint upon William J Hemelt for dft Matrixx Initiatives on 5/21/04 (MAP) (Entered: 12/13/2004)
01/18/2005	59	ORDER by Judge Mary H. Murguia granting Pla NECA-Fund"s motion to be appointed lead Pla, to appoint lead counsel, and to appoint liaison counsel is granted [Dkt #3-2, 3-3, 6-2, 6-3] FURTHER ORDERED denying Pla Sved group"s motion to be appointed lead pla, to appoint lead counsel, and to appoint liaison [Doc #7-2, 7-3, 10-2, 10-3] FURTHER ORDERED granting motion to substitute attorney David B Rosenbaum and Maureen Beyers of Osborn Maledon replacing James Condo of Snell & Wilmer (Michael Yoder and Amy Longo of O"Melveny & Meyers remain as co-counsel) by dft Matrixx Initiatives, dft Carl J Johnson, dft William J Hemelt [17-1] FURTHER ORDERED directing the Clk of Court to designate Pla James V Siracusano, individually and on behalf of all others similarly situated as named Pla in this action FURTHER ORDERED that the Court intends to resolve class certification on an expeditious basis ACCORDINGLY, setting a hearing re setting a schedule for

		class certification for 3:00 on 2/17/05 The Court directs Neca-Fund and Dft to meet and confer re a proposed schedule for class certification, addressing ddls for discovery and related issues. The partiers shall submit to the Court, preferably a joint proposed class certification sched order, nlt 2/10/05 (cc: all counsel) (MAP) (Entered: 01/18/2005)
01/21/2005	60	MOTION for admission pro hac vice as to Scott Saham, atty for movant NECA-IBEW [60-1] (MAP) (Entered: 01/25/2005)
01/21/2005	61	MOTION for admission pro hac vice as to Lucas F Olts, atty for movant NECA-IBEW [61-1] (MAP) (Entered: 01/25/2005)
01/26/2005		Pro Hac Vice $100 Fee Paid as to Lucas F Olts in 2:04-cv-00886 (BAS) Modified on 03/31/2005 (Entered: 01/26/2005)
01/26/2005		Pro Hac Vice $100 Fee Paid as to Scott H Saham in 2:04-cv-00886 (BAS) Modified on 03/31/2005 (Entered: 01/26/2005)
01/27/2005	62	ORDER by Judge Mary H. Murguia granting motion for admission pro hac vice as to Lucas F Olts, atty for movant NECA-IBEW [61-1] (cc: all counsel) (MAP) (Entered: 01/27/2005)
01/27/2005	63	ORDER by Judge Mary H. Murguia granting motion for

		admission pro hac vice as to Scott Saham, atty for movant NECA-IBEW [60-1] (cc: all counsel) (MAP) (Entered: 01/27/2005)
01/27/2005	64	MINUTE ORDER: Due to a conflict on the Court"s calendar, the Court ORDERS that the hearing re: setting a schedule for class certification be reset from February 17, 2005 to March 3, 2005 at 3:00 p.m. before the Honorable Mary H. Murguia. (cc: MHM, all counsel) [64-2] (KSB) (Entered: 01/27/2005)
02/08/2005	65	STIPULATION re Consolidated Amended Complaint by plas, dfts (MAP) (Entered: 02/14/2005)
02/24/2005	66	ORDER by Judge Mary H. Murguia that the hearing re scheduling class certification scheduled for 3/3/05 is vacated FURTHER ORDERED that Pla shall file a consolidated amended complaint on/before 3/4/05 FURTHER ORDERED that Dfts shall naswer or otherwise respond to the amended complaint on or before 4/4/05 FURTHER ORDERED that the parties will observe the standard briefing schedule provided in the Fed.R.Civ.P. and Local R.Civ.P. FURTHER ORDERED that Pla"s motion for class certification shall be filed w/in 30 days from the issuance of an Order by this Court

		(cc: all counsel) (MAP) (Entered: 02/24/2005)
03/04/2005	67	CONSOLIDATED AMENDED COMPLAINT by pla James V Siracusano [1-1]; terminating pla Stanley Sved, adding dft Timothy L Clarot (MAP) Modified on 05/19/2005 (Entered: 03/08/2005)
03/10/2005	68	(NOTICE OF) ERRATA by pla James V Siracusano to complaint (amended) [67-1] (MAP) (Entered: 03/21/2005)
03/15/2005	69	STIPULATION re Dfts" Motion to Dismiss Pla"s Consolidated Amendeed Complaint by plas, dfts (MAP) (Entered: 03/21/2005)
03/24/2005	70	ORDER by Judge Mary H. Murguia granting stipulation re Dfts" Motion to Dismiss Pla"s Consolidated Amended Complaint by plas, dfts. That Dfts shall file a pleading or motion responsive to Pla"s Consolidated Amended Complaint by 4/4/05; Pls ahll file an Opposition to any Motion to Dismiss by 4/25/05; Dfts shall file their Reply by 5/9/05 (cc: all counsel) (MAP) (Entered: 03/24/2005)
03/30/2005	71	RETURN OF SERVICE EXECUTED summons/complaint upon Mrs Clarot for dft Timothy L Clarot in 2:04-cv-00886on 3/25/05 (MAP) (Entered: 04/01/2005)
04/04/2005	72	MOTION to strike from Pla"s

		Consolidated Amended Complaint, paragraphs 30 and 49 in their entirety and paragraph 64 in part by dfts [72-1] (MAP) (Entered: 04/06/2005)
04/04/2005	73	MOTION to dismiss case w/prejudice by dfts [73-1] (MAP) (Entered: 04/06/2005)
04/04/2005	74	DECLARATION of Amy J. Longo in support of motion to dismiss case w/prejudice by dfts [73-1] and motion to strike from Pla"s Consolidated Amended Complaint, paragraphs 30 and 49 in their entirety, and paragraph 64 in part by dfts [72-1] by dfts (MAP) (Entered: 04/06/2005)
04/25/2005	75	RETURN OF SERVICE EXECUTED summons/complaint upon dft Timothy L Clarot in 2:04-cv-00886on 3/25/05 (SRB) (Entered: 04/25/2005)
04/25/2005	76	RESPONSE by pla to motion to strike from Pla"s Consolidated Amended Complaint, paragraphs 30 and 49 in their entirety, and paragraph 64 in part by dfts [72-1] (MAP) (Entered: 04/27/2005)
04/25/2005	77	RESPONSE by pla James V Siracusano to motion to strike from Pla"s Consolidated Amended Complaint, paragraphs 30 and 49 in their entirety, and paragraph 64 in part by dfts [72-1] (MAP) (Entered: 04/27/2005)

05/09/2005		Text not available. (Entered: 05/10/2005)
05/09/2005	78	REPLY by dfts in 2:04-cv-00886 to response to motion to strike from Pla"s Consolidated Amended Complaint, paragraphs 30 and 49 in their entirety, and paragraph 64 in part by dfts [72-1] (DMT) (Entered: 05/10/2005)
05/09/2005	79	REPLY by dfts in 2:04-cv-00886 to response to motion to dismiss case w/prejudice by dfts [73-1] (DMT) (Entered: 05/10/2005)
05/09/2005	80	MOTION for hearing on their motion to dismiss and motion to strike by dfts in 2:04-cv-00886 [80-1] (DMT) (Entered: 05/10/2005)
08/18/2005	81	Minute Order: The Court ORDERS granting the motion for hearing 80 . Oral argument as to the Motion to Strike 72 and the Motion to Dismiss 73 is scheduled on Wednesday, October 12, 2005 at 1:30 p.m. before the Honorable Mary H. Murguia. [This is a TEXT ONLY entry. There is no.pdf document attached.] (KSB) (Entered: 08/18/2005)
08/18/2005		Copy of document number 81, mailed to R. Abadou on this date. (KSB) (Entered: 08/18/2005)
09/26/2005	82	NOTICE of Change of Firm Address by Lucas F Olts, Scott H Saham: 655 West Broadway, Suite 1900; San Diego, CA 92101,

		Telephone: 619/231-1058. (DNH,) (Entered: 09/29/2005)
10/12/2005	83	Minute Entry for proceedings held before Judge Mary H Murguia: Motion Hearing held on 10/12/2005 re 72 Motion to Strike filed by Matrixx Initiatives, Inc., Carl J Johnson, and 73 Motion to Dismiss Case filed by Matrixx Initiatives, Inc., Carl J Johnson. (Court Reporter Merilyn Sanchez.) (KFZ) (Entered: 10/13/2005)
10/17/2005	84	TRANSCRIPT DESIGNATION AND ORDER FORM by NECA-IBEW for proceedings held on 10/12/2005 before Judge Mary H Murguia. (BAS,) (Entered: 10/18/2005)
10/20/2005	85	TRANSCRIPT DESIGNATION AND ORDER FORM by Matrixx Initiatives, Inc. for oral argument proceedings held on 10/12/2005 before Judge Mary H Murguia. (BAS,) (Entered: 10/24/2005)
11/14/2005	86	TRANSCRIPT of Motion Hearing Proceedings held on 10/12/2005 before Judge Mary H Murguia. Court Reporter: Merilyn A Sanchez. (BAS,) (Entered: 11/15/2005)
01/23/2006	87	NOTICE of Change of Address by Scott H Saham (Saham, Scott) (Entered: 01/23/2006)
03/08/2006	88	ORDER granting in part and denying in part 72 Motion to

		Strike FURTHER ORDERED granting 73 Motion to Dismiss. The First Amended Complaint is dismissed without prejudice. Signed by Judge Mary H Murguia on 12/15/05. (MAP,) (Entered: 03/08/2006)
03/08/2006	89	JUDGMENT that this Court having granted Defendants" Motion to Dismiss, Plaintiffs take nothing. This Complaint and action are hereby dismissed without prejudice.(MAP,) (Entered: 03/08/2006)
03/10/2006	90	Minute Order: The parties are hereby advised that the Order addressing doc. 72 and 73 was signed on December 15, 2005, but because adjustments associated with the recent transition to CM/ECF the order was not properly docketed. [This is a TEXT ONLY entry. There is no.pdf document attached.] (KSP) (Entered: 03/10/2006)
04/03/2006	91	NOTICE OF APPEAL to 9th Circuit, re 89 Judgment, 88 Order by James V Siracusano. (Attachments: # 1 Civil Appeals Docketing Statement)(Saham, Scott) Modified on 4/5/2006 (LSP). DOCKET TEXT MODIFIED TO CORRECT DOCUMENT LINKAGE. (Entered: 04/03/2006)
04/04/2006		USCA Appeal Fees received $ 255

		receipt number PHX041352 re 91 Notice of Appeal filed by James V Siracusano, (LSP) (Entered: 04/05/2006)
04/05/2006		COPY of CADS Sent re 91 Notice of Appeal: Civil Appeals Docketing Statement sent to 9th Circuit on this date; copy attached to Notice of Appeal; (NOTE: original must be submited for the Ninth Circuit) (LSP) (Entered: 04/05/2006)
04/05/2006		Appeal Remark re 91 Notice of Appeal: Member case number CV 04-1012 PHX-MHM notated on Copy of Notice of Appeal forwarded to the Ninth Circuit and Ramzi Abadou (LSP) (Entered: 04/05/2006)
04/05/2006	92	Notice of Appeal Notification Form; Notice of Appeal and copy of docket sheet transmitted to Ninth Circuit and all parties re 91 Notice of Appeal (LSP) (Entered: 04/05/2006)
04/05/2006		ORIGINAL CADS Sent re 91 Notice of Appeal: Civil Appeals Docketing Statement sent to 9th Circuit on this date. (LSP) (Entered: 04/05/2006)
04/18/2006	93	Ninth Circuit Case Number 06-15677 for 91 Notice of Appeal. NOTE: Case Number taken from Time Schedule Order to Court Reporter Merilyn Sanchez (LSP) (Entered: 04/18/2006)

04/24/2006	94	Ninth Circuit Case Number 06-15677 for 91 Notice of Appeal. (LSP) (Entered: 04/24/2006)
05/02/2006	95	APPEAL TRANSCRIPT REQUEST by James V Siracusano for proceedings held on 10/12/05 before Judge Mary H Murguia, re 91 Notice of Appeal Transcript filed as of 11/14/2005. (BAS,) (Entered: 05/03/2006)
05/08/2006	96	CERTIFICATE OF RECORD TRANSMITTED TO 9TH CIRCUIT COURT OF APPEALS re 91 Notice of Appeal (LSP) (Entered: 05/08/2006)
09/15/2007	97	Notice re Firm Name Change by NECA-IBEW (Saham, Scott) (Entered: 09/15/2007)
05/15/2009	98	Transmitted Record on Appeal to 9th Circuit re 91 Notice of Appeal. Number of Volumes of Clerks Records: 2; Number of Bulky Documents: 2; Docket Numbers of Bulky Documents: 9, 74; Number of Transcripts: 2; Docket Numbers of Transcripts: 55, 86; Number of Expandos: 1; all other documents available electronically through PACER. (LAD) (Entered: 05/15/2009)
10/22/2009	99	ORDER of 9th Circuit, Appellees" motion to take judicial notice, filed October 5, 2006, and appellees" supplemental request for judicial notice, filed June 8, 2009, are

		denied; appeal case number 06-15677, as to 91 Notice of Appeal filed by James V Siracusano (DMT,) (Entered: 10/22/2009)
03/22/2010	100	Notice re Firm Name Change by NECA-IBEW (Saham, Scott) (Entered: 03/22/2010)

APPENDIX B

General Docket
United States Court of Appeals for the Ninth Circuit

Court of Appeals Docket #: 06-15677 **Nature of Suit:** 3850 Securities, Commodities, Exchange Siracusano v. Maatrixx Initiatives, et al **Appeal From:** U.S. District Court for Arizona, Phoenix **Fee Status:** Paid	**Docketed:** 04/13/2006 **Termed:** 10/28/2009
Case Type Information: **1)** civil **2)** private **3)** null	
Originating Court Information: **District:** 0970-2 : CV-04-00886-MHM **Court Reporter:** Merilyn A. Sanchez, Court Reporter **Trial Judge:** Mary H. Murguia, District Judge **Date Filed:** 04/27/2004 **Date Order/Judgment:** 03/08/2006	**Date NOA Filed:** 04/03/2006

District: 0970-2 : CV-04-01012-MHM	
Trial Judge: Mary H. Murguia, District Judge	**Date NOA Filed:**
Date Filed: 05/19/2004	
Date Order/Judgment: 03/08/2006	04/03/2006
Prior Cases: None	
Current Cases: None	

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NECA-IBEW Claimant - Appellant,	Joseph David Daley, Attorney Direct: 619-231-1058 [COR LD NTC Retained] (see above) Andrew S. Friedman, Attorney Direct: 602-776-5944 [COR LD NTC Retained] (see above) Samuel H. Rudman, Esquire, Attorney Direct: 613/367-7100 [COR LD NTC Retained] (see above) Scott Saham, Esquire Direct: 619/231-1058 [COR LD NTC Retained] (see above)
v.	
MAATRIXX INITIATIVES, INC.	Maureen Beyers, Esquire, Attorney

Defendant - Appellee,	Direct: 602-640-9000 [COR LD Retained] Osborn Maledon, P.A. 2929 North Central Avenue 21st Floor Phoenix, AZ 85012-2793 James R. Condo, Esquire, Attorney Direct: 602-382-6353 [COR LD NTC Retained] Snell & Wilmer L.L.P. One Arizona Center 400 E. Van Buren Phoenix, AZ 85004-2202 Amy Jane Longo, Attorney Direct: 213-430-8351 [COR LD NTC Retained] O'MELVENY & MEYERS 400 South Hope Street Los Angeles, CA 90071-2899 Molly Magnuson, Attorney

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CARL J. JOHNSON Defendant - Appellee,	Maureen Beyers, Esquire, Attorney Direct: 602-640-9000 [COR LD Retained] (see above) James R. Condo, Esquire, Attorney Direct: 602-382-6353 [COR LD NTC Retained] (see above) Amy Jane Longo, Attorney Direct: 213-430-8351 [COR LD NTC Retained] (see above) Molly Magnuson, Attorney Direct: 949-760-9600 [COR LD Retained] (see above) David B. Rosenbaum, Attorney [COR LD NTC Retained]

	(see above) Michael G. Yoder, Attorney Direct: 949-760-9600 [COR LD NTC Retained] (see above)
WILLIAM J. HEMELT Defendant - Appellee,	Maureen Beyers, Esquire, Attorney Direct: 602-640-9000 [COR LD Retained] (see above) James R. Condo, Esquire, Attorney Direct: 602-382-6353 [COR LD NTC Retained] (see above) Amy Jane Longo, Attorney Direct: 213-430-8351 [COR LD NTC Retained] (see above) Molly Magnuson, Attorney

	Direct: 949-760-9600 [COR LD Retained] (see above) David B. Rosenbaum, Attorney [COR LD NTC Retained] (see above) Michael G. Yoder, Attorney Direct: 949-760-9600 [COR LD NTC Retained] (see above)

JAMES SIRACUSANO, Individually and on behalf of all others similarly situated, Plaintiff - Appellant, NECA-IBEW, Claimant - Appellant, v. MAATRIXX INITIATIVES, INC.; CARL J. JOHNSON; WILLIAM J. HEMELT, Defendants - Appellees.

04/13/2006	2	DOCKETED CAUSE AND ENTERED APPEARANCES OF COUNSEL. CADS SENT (Y/N):

		NO. setting schedule as follows: appellant's designation of RT is due 4/17/06, ; appellee's designation of RT is due 4/25/06,, ; appellant shall order transcript by 5/5/06, ; court reporter shall file transcript in DC by 6/5/06, ; certificate of record shall be filed by 6/12/06 ; appellant's opening brief is due 7/24/06, ; appellees' brief is due 8/21/06,, ; appellants' reply brief is due 9/5/06, ; [06-15677] (MF)
04/13/2006	4	Filed Joseph D. Daly for Appellant NECA-IBEW, Appellant James Siracusano Civil Appeals Docketing Statement served on 4/3/06 (to CONFATT) [06-15677] [06-15677] (MF)
04/13/2006	5	Filed Statement of Representation by Josseph D. Daley, csl for aplts; served on 4/3/06 (CASEFILE) [06-15677] (MF)
04/21/2006	8	Filed order CONFATT (epm) This case is under consideration for inclusion in the Mediation Program. A settlement assessment conf will be held by tele on 5/19/06 at 10:00 a.m. PST .... The briefing schedule previously set by the court remains in effect. [06-15677]

		(KKW)
05/03/2006	9	Filed Court Reporter's notice of order of transcript. RT ordered 5/1/06; [06-15677] (KKW)
05/11/2006	10	Filed certificate of record on appeal RT filed in DC 11/14/05 [06-15677] (KKW)
05/24/2006	12	Filed order CONFATT (PWS) ...The court has determined that this appeal will not be selected for inclusion in the Mediation Program. The briefing schedule set forth in tht court's order filed 4/13/06 shall remain in effect... [06-15677] (KKW)
07/13/2006	13	14 day oral extension by phone of time to file Appellant James Siracusano, Appellant NECA-IBEW brief. THe opening brief is due 8/7/06; the answering brief is due 9/6/06; the optional reply brief is due 14 days after service of the answering brief. [06-15677] (GS)
08/09/2006	14	Filed original and 15 copies Appellant James Siracusano, Appellant NECA IBEW opening brief (Informal: No) 53 pages and five excerpts of record ; served on 8/7/06 [06-15677] (KKW)
08/16/2006	15	14 day oral extension by phone to

		file Appellee's answering brief [06-15677]. Appellees' brief due 9/20/06. The optional reply brief is due 14 days after service of the answering brief. (LB)
09/11/2006	16	Filed Matrixx Initiatives, Carl J. Johnson, William J. Hemelt motion to extend time to file appellee's brief served on 9/11/06 PROMO. (KKW)
09/15/2006	18	Filed order (Appellate Commissioner) The aples' mtn for an extension of time to file the ans brief is granted. The ans brief is due 10/4/06. The opt rpy brief is due 14 days after service of the ans brief. (PROMO) [06-15677] (KKW)
10/05/2006	19	Filed Matrixx Initiatives, Carl J. Johnson, William J. Hemelt motion to take judicial notice served on 10/4/06 PROMO. (KKW)
10/05/2006	20	Filed original and 15 copies appellee Matrixx Initiatives, Carl J. Johnson, William J. Hemelt's 63 pages brief, 1 vol. Exc. ; served on 10/4/06 [06-15677] (KKW)
10/10/2006	23	Filed order (Deputy Clerk: gss) The aples' request for judicial notice, any response and any further request for judicial notice shall be referred to the merits panel for whatever treatment the

		panel deems appropriate. [06-15677] (KKW)
10/13/2006	24	Filed Appellant James Siracusano, Appellant NECA-IBEW's motion to extend time to file reply brief served on 10/12/06 PROMO. [06-15677] (KKW)
10/18/2006	26	Filed order (Deputy Clerk: gss) granting appellant's motion to extend time to file reply brief. appellants' reply brief is now due 11/13/06, ; [06-15677] (KKW)
11/15/2006	28	Filed original and 15 copies James Siracusano, NECA-IBEW reply brief, (Informal: n) 31 pages; served on 11/13/06 [06-15677] (GR)
07/17/2007	29	Calendar check performed [06-15677] (MW)
09/13/2007	30	Received notice of law firm name change from Joseph D. Daley. CASEFILE (GR)
06/16/2008	31	Filed Appellants' additional citations. Served on 06/13/2008. (records for merits panel) (JE)
06/26/2008	32	Filed Appellee's response to aplt's additional citations. Served on 06/25/2008. (records for merits panel) (JE)
08/26/2008	33	Filed Appellees William J. Hemelt, Carl J. Johnson and Maatrixx Initiatives, Inc.

		additional citations. Served on 08/25/2008. (records for merits panel) (MT)
09/18/2008	34	Filed Appellants NECA-IBEW and James Siracusano additional citations. Served on 09/17/2008. (records for merits panel) (RL)
10/06/2008	35	Filed Appellees William J. Hemelt, Carl J. Johnson and Maatrixx Initiatives, Inc. response to Appellants' additional citations. Served on 10/03/2008. (records for merits panel) (RL)
01/29/2009	36	Filed (ECF) Appellees William J. Hemelt, Carl J. Johnson and Maatrixx Initiatives, Inc. citation of supplemental authorities. Date of service: 01/21/2009. [6778392] (MM)
01/29/2009	37	Calendar materials being prepared. (AM)
02/04/2009	38	CALENDARED: 04/14/2009 9:00 AM San Francisco, CA Courtroom 3 [(MW)
02/24/2009	39	Notice of Oral Argument on APRIL 14, 2009 Calendar. Please return ACKNOWLEDGEMENT OF HEARING NOTICE form to: SAN FRANCISCO Office. Attention: Please open attached documents to view details about your case. (AM)

02/27/2009	40	Notice of Oral Argument on APRIL 14, 2009 Calendar. Please open attached document to view MAXIMUM ARGUMENT TIME PER SIDE for your case. (AM)
03/05/2009	41	Filed (ECF) Appellees William J. Hemelt, Carl J. Johnson and Maatrixx Initiatives, Inc. Motion to continue hearing of case until 04/21/2009 at 09:00 am. Date of service: 03/05/2009. [6835066] (MM)
03/09/2009	42	Filed clerk order (Deputy Clerk: SC): Appellees' motion to continue oral argument is GRANTED. The clerk is directed to place this case before the next available panel. (WL)
03/27/2009	44	Calendar materials being prepared. [05-72267, 05-76507, 07-17197, 06-15677, 07-17206, 09-15230] (AM)
04/01/2009	45	CALENDARED: 06/09/2009 9:00 AM San Francisco, CA Courtroom 1 [07-17197, 06-15677, 07-17206, 09-15230] (AM)
04/24/2009	46	Notice of Oral Argument on JUNE 9, 2009 Calendar. Please return ACKNOWLEDGEMENT OF HEARING NOTICE form to: SAN FRANCISCO Office. Open attached documents to view details about your case. (AM)

05/29/2009	47	Filed clerk order (Deputy Clerk:PA): Permission is GRANTED to Courtroom View Network ("CVN") to video-record oral argument in digital format the case captioned above, scheduled to be heard on Tuesday, June 9, 2009, in San Francisco, CA, provided that CVN agrees to provide the court, without charge, a copy of the recording, in a format agreeable to the court, with the understanding that the court will put the recording on our website and will make it available to the public. (PA)
06/08/2009	48	COURT DELETED ENTRY. REPLACED BY [49] below. Original Text: Submitted (ECF) Supplemental brief for review. Submitted by Appellees William J. Hemelt, Carl J. Johnson and Maatrixx Initiatives, Inc.. Date of service: 06/08/2009. [6948756] (MM)
06/08/2009	49	Filed (ECF) Appellees William J. Hemelt and Carl J. Johnson Supplemental Motion to take supplemental judicial notice in in Support of Defendants-Appellees' Answering Brief. Date of service: 06/08/2009. [6948914] COURT- ENTERED FILING TO REPLACE [6948756] from

		06/08/2009; also replaced PDF with searchable version. (ASW)
06/09/2009	50	ARGUED AND SUBMITTED TO MARY M. SCHROEDER, A. WALLACE TASHIMA and CARLOS T. BEA. (DO)
06/17/2009	51	Filed (ECF) Appellants NECA-IBEW and James Siracusano citation of supplemental authorities. Date of service: 06/17/2009. [6960290] (JDD)
06/24/2009	52	Filed (ECF) Appellee Maatrixx Initiatives, Inc. Correspondence: Response to Plaintiffs Supplemental Authority Citation Letter. Date of service: 06/24/2009 [6967565] (MM)
10/21/2009	53	Filed order (MARY M. SCHROEDER, A. WALLACE TASHIMA and CARLOS T. BEA) Appellees' motion to take judicial notice, filed October 5, 2006, and appellees' supplemental request for judicial notice, filed June 8, 2009, are denied. [7103461] (SC)
10/28/2009	54	FILED OPINION (MARY M. SCHROEDER, A. WALLACE TASHIMA and CARLOS T. BEA) REVERSED AND REMANDED. , Judge: AWT Authoring. FILED AND ENTERED JUDGMENT. [7110179] (RP)

11/12/2009	55	COURT DELETED ENTRY. Filer resubmitted in [56] using the correct category. Original text: Filed (ECF) Appellees William J. Hemelt, Carl J. Johnson and Maatrixx Initiatives, Inc. petition for rehearing en banc (from 10/28/2009 opinion). Date of service: 11/12/2009. [7128564] (MB)
11/13/2009	56	Filed (ECF) Appellees William J. Hemelt, Carl J. Johnson and Maatrixx Initiatives, Inc. petition for panel rehearing and petition for rehearing en banc (from 10/28/2009 opinion). Date of service: 11/12/2009. [7129921] (MB)
12/23/2009	57	Filed order (MARY M. SCHROEDER, A. WALLACE TASHIMA and CARLOS T. BEA) The panel has voted to deny the petition for panel rehearing. Judges Schroeder and Bea vote to deny the petition for rehearing en banc and Judge Tashima so recommends. The full court has been advised of the petition for rehearing en banc and no judge of the court has requested a vote on en banc rehearing. See Fed. R. App. P. 35(f). The petition for panel rehearing and the petition for rehearing en banc are denied.

		[7173625] (WL)
12/29/2009	58	Filed (ECF) Appellees William J. Hemelt, Carl J. Johnson and Maatrixx Initiatives, Inc. Motion to stay the mandate. Date of service: 12/29/2009. [7177835] (DBR)
12/30/2009	59	Filed (ECF) Appellants NECA-IBEW and James Siracusano response opposing motion (Motion (ECF Filing) ,Motion (ECF Filing) motion to stay the mandate). Date of service: 12/30/2009. [7179556] (JDD)
01/05/2010	60	Filed order (MARY M. SCHROEDER, A. WALLACE TASHIMA and CARLOS T. BEA) Defendants-appellees' motion to stay mandate pending application for certiorari is granted, and issuance of the mandate is stayed pursuant to and for the period specified in Fed. R. App. P. 41(d)(2)(B). [7183206] (SC)
03/25/2010	61	Received Aples' courtesy copy of filing Cert in the SC [7279157] (GV)
03/26/2010	63	Received notice from the Supreme Court: petition for certiorari filed on 03/24/2010. Supreme Court Number 09-1156. [7280263] (GV)

03/26/2010	64	Filed (ECF) Appellants NECA-IBEW and James Siracusano Correspondence: Notice of Firm Name Change. Date of service: 03/26/2010 [7280684] (JDD)
06/21/2010	65	Received notice from the Supreme Court. Petition for certiorari GRANTED on 06/14/2010. Supreme Court Number 09-1156. [7379544] (GV)

APPENDIX C

CONSOLIDATED AMENDED COMPLAINT

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Lead Counsel for Plaintiffs

UNITED STATES DISTRICT COURT
DISTRICT OF ARIZONA

JAMES V. SIRACUSANO, On Behalf of Himself and All Others Similarly Situated,	)	Civ. No. 04-0886-PHX-DKD
	)	(Consolidated)
	)	CLASS ACTION
Plaintiff,	)	
	)	**CONSOLIDATED AMENDED COMPLAINT FOR VIOLATION OF THE FEDERAL SECURITIES LAWS**
vs.	)	
MATRIXX INITIATIVES INC.; CARL J. JOHNSON; WILLIAM J. HEMELT; and TIMOTHY L. CLAROT,	)	
Defendants.	)	

INTRODUCTION

1. This is a federal securities class action on behalf of purchasers of the publicly traded securities of Matrixx Initiatives Inc. ("Matrixx" or the "Company") between October 22, 2003 and February 6, 2004, inclusive (the "Class Period").

2. Defendant Matrixx is engaged in the development, manufacture and marketing of over-the-counter pharmaceuticals. During the Class Period, Matrixx only directly employed 15 people as it chose to outsource many of its corporate functions. Through its main operating wholly-owned subsidiary Zicam, LLC, Matrixx sells several products under the Zicam name, all of which are used for the treatment of the common cold and associated symptoms. The Zicam brand is Matrixx's core brand and, during the Class Period, made up both 100% of the Company's net sales, gross profit and growth. One of Matrixx's most popular products is the Zicam Cold Remedy, which accounted for approximately 70% of Zicam Class Period sales. This product was marketed as "the only nasal product on the market that has been clinically proven to reduce the duration of the common cold." Zicam Cold Remedy can be applied in several forms, including a nasal spray and a gel. Zicam Cold Remedy, and other of the Company's cold-fighting products, rely on a compound called zinc gluconate as the active ingredient.

3. In September 2003, prior to the start of the Class Period, defendants learned that numerous users of their Zicam product had experienced anosmia, which is a total loss of smell and that, as detailed herein, medical researchers at the

University of Colorado School of Medicine had prepared a presentation for the fall meeting of the American Rhinologic Society which identified 10 patients who had lost their sense of smell after using Zicam including a detailed case study of one of those patients.

4. Despite their knowledge of the University of Colorado research and the anosmia cases, defendants failed to disclose this material information in any public statement or Securities and Exchange Commission ("SEC") filing. Instead, defendants instituted measures to prevent the University of Colorado Researchers from referencing Zicam in any report of their findings. Specifically, Matrixx informed Dr. Jafek that "as a legal matter" he did "not have their permission to use their company name or product trademarks" in the poster reporting the University of Colorado research at the American Rhinologic Society September 20, 2003 Fall Science meeting. In response to the Company's demand, Dr. Jafek deleted any reference to Zicam or Matrixx from the poster presenting his research at the American Rhinologic Society meeting.

5. Throughout the Class Period, Matrixx touted the growth of its business, reporting triple-digit growth in revenue and income, highlighting the increased success of its Zicam cold remedies without any disclosure of the University of Colorado Research or the known adverse health effects of Zicam. The Company's Class Period representations to the investing public were, materially false and misleading when made because they failed to disclose the findings of the University of Colorado School of Medicine researchers and that the Company was already subject to lawsuits alleging

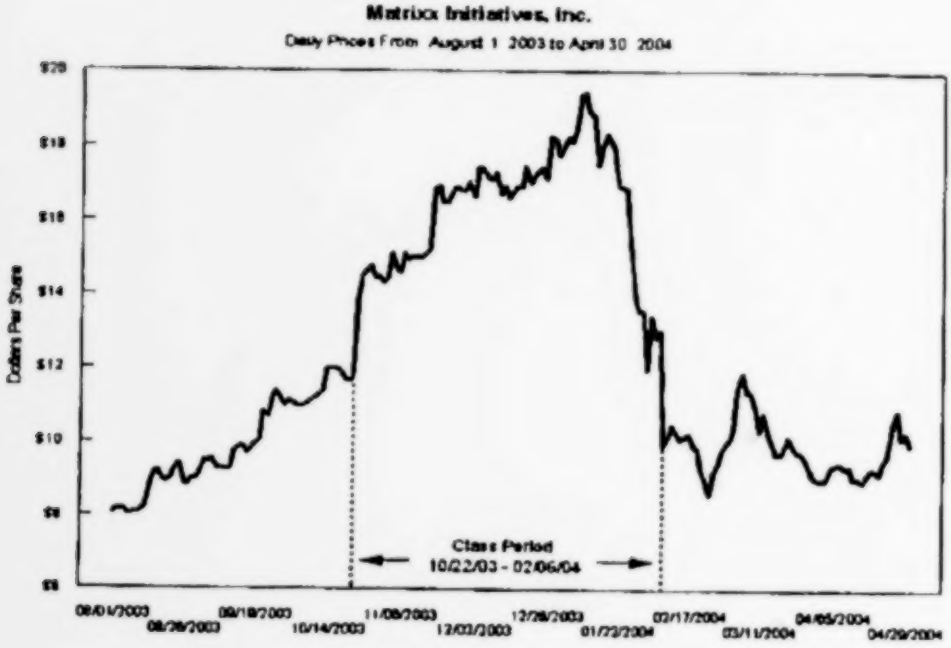
that the Company's zinc-based products had caused anosmia. In addition, the Company's SEC filings purported to warn investors that the potential for product liability lawsuits presented a material risk to the Company, but failed to disclose that such lawsuits had *already* been filed. The first action was filed on October 14, 2003, in the United States District Court for the Western District of Michigan (No. 4:03-cv-0146-HWB), prior to the beginning of the Class Period.

6. Then, on January 30, 2004, an article published over the *Dow Jones Wire* revealed that the FDA was investigating a potential link between Matrixx products and anosmia and that three product liability lawsuits had alleged that the Company's product had caused the plaintiffs to develop anosmia.

7. On February 2, 2004, the Company, seeking to limit the damage to its stock price issued a press release representing that "statements alleging that intranasal Zicam products cause anosmia (loss of smell) are completely unfounded and misleading." The Company further represented that "[i]n no clinical trial of intranasal zinc gluconate gel products has there been a single report of lost or diminished olfactory function (sense of smell)." Such statements were materially false and misleading because, as the Company would later admit, it had conducted no clinical study examining the relationship between zinc gluconate gel and anosmia and that defendants had been informed of research linking both Zinc generally and their product specifically to loss of smell, by researchers at the University of Colorado School of Medicine and a

specialist at the Smell & Taste Research Foundation, Ltd.

8. On February 6, 2004, a nationally-broadcast story on *Good Morning America* which featured Dr. Jafek and his research, reported the adverse health risks associated with Zicam and that at least four lawsuits were filed alleging that the Company's products had caused anosmia and that numerous similar actions were expected to be filed. In reaction to the *Good Morning America* story featuring Dr. Jafek and his findings, the price of Matrixx common stock plummeted, falling from $13.05 per share on February 5, 2004, to close at $9.94 per share on February 6 - a one-day drop of 23.8% on unusually heavy trading volume.



9. On February 6, 2004, Matrixx issued a press release entitled "Reaffirm[ing] safety of intranasal Zicam Cold Remedy." This statement as well as each of the Company's earlier statements regarding the safety of Zicam, were materially false and misleading as defendants failed to disclose the existence of the University of Colorado School of Medicine findings or the existence of numerous users of Zicam who were experiencing a total loss of smell.

10. On March 4, 2004, reporter John Ferrugia, who had been the reporter on the *Good Morning America* segment, reported, on news website *TheDenverChannel.com* (an affiliate of ABC News), that "Zicam Admits No Studies Done on Loss of Smell." According to the article, "[t]he makers of the nationally advertised cold remedy Zicam now admit that they don't know if their nasal gel could cause loss of smell."

JURISDICTION AND VENUE

11. The claims asserted herein arise under and pursuant to §§10(b) and 20(a) of the Securities Exchange Act of 1934 ("Exchange Act") 15 U.S.C. §§78j(b) and 78t(a) and Rule 10b-5 promulgated thereunder by the SEC 17 C.F.R. §240.10b-5.

12. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§1331 and 1337 and §27 of the Exchange Act 15 U.S.C. §78aa.

13. Venue is proper in this district pursuant to §27 of the Exchange Act and 28 U.S.C. §1391(b). Matrixx maintains its principal and executive offices in this district and many of the acts charged herein, including the preparation and dissemination of materially false and misleading

information, occurred in substantial part in this district.

14. In connection with the acts alleged in this complaint, defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications and the facilities of the national securities markets.

PARTIES

15. Lead Plaintiff NECA-IBEW PENSION FUND (THE DECATUR PLAN) purchased Matrixx publicly traded securities during the Class Period, as detailed in the certification previously filed with the Court and has been damaged thereby.

16. Defendant Matrixx is organized under the laws of the State of Delaware and maintains its principal executive offices at 4742 North 24th Street, Suite 455, Phoenix, Arizona 85016.

17. Defendant Carl J. Johnson ("Johnson") was Matrixx's Chief Executive Officer, President and a director, throughout the Class Period.

18. Defendant William J. Hemelt ("Hemelt") was Matrixx's Chief Financial Officer and Executive Vice President.

19. Defendant Timothy L. Clarot ("Clarot") was Matrixx's Vice President and Director of Research and Development.

20. Defendants Johnson, Hemelt and Clarot are referred to collectively herein as "Individual Defendants."

21. During the Class Period, each of the Individual Defendants, as senior executive officer

and/or director of Matrixx was privy to confidential and proprietary information concerning Matrixx, its operations, finances, financial condition, present and future business prospects. The Individual Defendants also had access to material adverse non-public information concerning Matrixx, as discussed in detail below. Because of their positions with Matrixx, the Individual Defendants had access to non-public information about its business, finances, products, markets and present and future business prospects via access to internal corporate documents, conversations and connections with other corporate officers and employees, attendance at management and Board of Directors meetings and committees thereof and via reports and other information provided to them in connection therewith. Because of their possession of such information, the Individual Defendants knew or recklessly disregarded the fact that adverse facts specified herein had not been disclosed to and were being concealed from, the investing public.

22. Each of the defendants is liable as a direct participant in and co-conspirator with respect to the wrongs complained of herein. In addition, defendants Johnson and Hemelt, by reason of their status as senior executive officers and directors were each a "controlling person" within the meaning of §20 of the Exchange Act and had the power and influence to cause the Company to engage in the unlawful conduct complained of herein. Because of their positions of control, defendants Johnson and Hemelt were able to and did, directly or indirectly, control the conduct of Matrixx's business.

23. The Individual Defendants, because of their positions with the Company, controlled and/or

possessed the authority to control the contents of its reports, press releases and presentations to securities analysts and through them, to the investing public. The Individual Defendants were provided with copies of the Company's reports and press releases alleged herein to be misleading, prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Thus, the Individual Defendants had the opportunity to commit the fraudulent acts alleged herein.

CONCEALED ADVERSE INFORMATION REGARDING ZICAM

24. Defendants were aware prior to the start of the Class Period that numerous users of their Zicam product had experienced a rare condition known as anosmia. Numerous cases of anosmia were observed by researchers at the University of Colorado School of Medicine, Department of Otolaryngology, The Rocky Mountain Taste and Smell Center ("RMTSC")[1] and the Smell & Taste Treatment and Research Foundation Ltd.

25. Dr. Alan Hirsch M.D., F.A.C.P., Neurological Director of the Smell & Taste Treatment and Research Foundation, Ltd., first recognized the possible link between Zicam nasal gel and a loss of smell in a cluster of his patients in 1999 shortly after the product came on the market. In December 1999, Hirsch called Matrixx's customer

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[1] The RMTSC, a NIH Program Project Grant, is a collaborative research effort by the Departments of Cellular & Structural Biology and Otolaryngology at the University of Colorado School of Medicine which is dedicated to the study of taste and smell under normal and diseased conditions in human and animal models.

service line to inquire into the amount of zinc contained in Zicam nasal gel. Hirsch spoke with a Mr. Laundau. Hirsch told Laundau about at least one patient who developed anosmia after using Zicam in the absence of a cold. Hirsch also mentioned to Laundau that previous studies had demonstrated that intranasal application of zinc could be problematic, but Laundau indicated that he was not aware of these studies. Hirsch further told Laundau that he was willing to conduct a clinical study on the issue, but was "told 'no' at that time."

26. In September of 2002, Timothy L. Clarot, Matrixx's Vice President, Research and Development[2] called Miriam R. Linschoten, Ph.D., of the University of Colorado Health Sciences Center concerning Zicam customer complaints related to loss of smell. During this call, Linschoten referenced previous studies linking zinc sulfate to loss of smell. Linschoten expressed her concern to Clarot over the lack of information regarding the Zicam product, that is available over-the-counter, with no warning that it could cause users to suffer a loss of smell. Clarot had called Linschoten because one of the several patients she had treated at the RMTSC for loss of smell after she had used Zicam, had also complained to Matrixx. In addition to her patient, Clarot informed Linschoten that Matrixx had also received complaints from other customers who experienced a loss of smell following use of Zicam nasal gel. Matrixx had received customer complaints of loss of smell as early as 1999. Linschoten asked

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[2] According to the Matrixx website Timothy L. Clarot oversees regulatory compliance activities, supply chain management, materials and product development, information technology and consumer affairs.

Clarot whether Matrixx had done any studies. Clarot responded that Matrixx had not, but that it had hired a consultant to review the product. Linschoten mentioned existing studies that linked zinc sulfate to loss of smell, but Clarot gave her the impression that he had not heard of these studies. Linschoten then offered to send Clarot information regarding these studies.

27. On September 20, 2002, Linschoten sent an email as promised to Clarot which included abstracts on the link between zinc sulfate and loss of smell. Zinc's toxicity had been confirmed by studies from the 1930s and work with fish in the early 80s. Linschoten received a phone call from Clarot not too long after she sent her September 20, 2002 email. Clarot inquired in this call as to whether she would participate in animal studies that Matrixx was planning to conduct. Linschoten responded that she did not want to participate, as she focuses on human research and not animal research.

28. As of September of 2003, Dr. Bruce Jafek of the University Colorado School of Medicine had observed 10 patients suffering from anosmia following Zicam use. Dr. Jafek, Dr. Linschoten and a colleague planned to submit their findings via a September 20, 2003 poster presentation to the American Rhinologic Society. Prior to the meeting scheduled for September 20, 2003, the American Rhinologic Society posted abstracts of scheduled presentations. Jafek, Linschoten and Murrow's abstract, entitled, "Zicam® Induced Anosmia," was posted along with the other scheduled presentation abstracts. The University of Colorado School of Medicine research provided a detailed description of one of the patients they had diagnosed with anosmia

following Zicam use. A 55 year old man with previously normal taste and smell who had developed clear rhinitis and congestion and treated himself with Zicam. On spraying his nose, he noted severe burning. This was followed immediately by loss of smell. In addition to the one detailed case, the University of Colorado researchers reported 10 other Zicam users with similar symptoms as of September of 2003.

29. On September 12, 2003, Matrixx sent a letter to Jafek stating that he did not have permission to use Matrixx's name or the names of its products. The letter was signed by Clarot. Jafek responded to Matrixx after consulting with the university attorney, seeking permission to use the names. Matrixx responded with another letter, "no." Thus, instead of disclosing this critical research to the public, defendants demanded that the University of Colorado researchers cease referring to Zicam in their poster describing their research. At that point, Jafek had to physically cut out all instances of the word "Zicam" in his poster presentation. The poster was presented to the American Rhinologic Society without specifically referring to the product. Jafek's findings regarding Zicam were ultimately disclosed to the public on February 6, 2004 on *Good Morning America.*

30. As of April of 2004, Dr. Jafek had evaluated over 100 cases of anosmia following Zicam use. Dr. Linschoten estimates that she has been in contact with approximately 65 patients who have experienced a loss of smell following use of Zicam nasal gel. She has "no doubt" that Zicam has an "immediate effect." The patients she has been in contact with complain of an "immediate, severe

burning" immediately following use of Zicam nasal gel, followed by a loss of smell. Some of her patients partially regained their sense of smell after a few months, but none of her patients have "completely recovered yet." Dr. Jafek's and Dr. Linschoten's findings that "[zinc ions are toxic to olfactory epithelium" and that "[r]eports of severe hyposmia with parosmia or anosmia appear to be related to the intranasal use of zinc gluconate [Zicam Cold Remedy]" were later published in the May/June issue of the *American Journal of Rhinology*.

31. Both Drs. Jafek and Hirsch have observed that the Zicam nasal spray does reach the upper area of the nasal cavity where smell reception occurs. Dr. Jafek observed that Zicam nasal gel would "hit the ceiling" if opened and squeezed. Late in 2002 Zicam introduced a cold remedy swab product which when used would not be propelled into the upper area of the nasal cavity.

MATERIALLY FALSE AND MISLEADING STATEMENTS DURING THE CLASS PERIOD

32. On October 22, 2003, Matrixx issued a press release announcing its operational results for the third quarter of 2003. According to the release, net sales increased by 164% over the third quarter of 2002, while net income nearly tripled:

> Matrixx Initiatives, Inc. . . . developer and distributor of the expanded line of Zicam(®) products, today announced net sales of $13.4 million for the third quarter of 2003, a 163 percent increase versus $5.1 million in the comparable quarter of 2002. Net income for the

> quarter was $2.8 million or $0.29 per share, versus $1.0 million, or $0.11 per share for the third quarter of 2002.
>
> Net sales for the nine month period ended September 30, 2003 were $25.3 million, a 111 percent increase over the $12.0 million reported for the comparable nine month period last year. Net income for the first nine months of this year increased 114 percent to $2.3 million, or $0.25 per share, compared to $1.1 million, or $0.11 per share, for the comparable period last year.

Defendant Johnson commented on the favorable results, highlighting the efficacy of the Zicam products:

> "The financial results for the third quarter and nine month period are clear indications that the execution of our strategic business plan has continued on track. We are solidly profitable and cash flow positive while having made substantial investments in advertising, marketing and research and development. These targeted investments are translating into expanded brand awareness and product acceptance by an increasingly sophisticated consumer market. We are very pleased with our results."
>
> * * *
>
> Mr. Johnson continued, "The Zicam brand is poised for growth in the

> upcoming cough and cold season with improved retail exposure by virtue of three unique oral delivery forms of our Zicam Cold Remedy product, the resumption of our television advertising campaigns in recent weeks and the momentum from last year's successful season. Additionally, our retail partners have come to rely on the Zicam brand not only as an efficacious product for their customers, but also for the profitability that Zicam branded products produce for their respective bottom-lines."

These statements were materially false and misleading because the defendants were aware but failed to disclose that Zicam posed a material health risk to consumers, as numerous users of the Zicam product had suffered a complete loss of smell. Defendants were aware as of September 2003, that researchers at the University of Colorado had linked Zicam and its operative ingredient to anosmia.

33. On October 23, 2003, defendants convened a conference call with financial analysts following the Company. During the conference call defendant Johnson stated that "retail results through October suggest that retail sales . . . are up 95%" and that "we are extremely encouraged at this point in time" as the Company has "very strong momentum going into the upcoming cough and cold season." Johnson further reiterated that:

> [W]hat lies behind these results is a unique product in the Zicam product line. A product that offers a unique

> benefit, the ability for consumers to actually reduce the duration and severity of the common cold, not just mask the symptoms.

These statements were materially false and misleading as defendants were aware, but failed to disclose, that researchers at the University of Colorado had reported a link between Zicam and anosmia and that use of Zicam posed a material health risk to consumers, which when disclosed would adversely affect the Company's business.

34. Defendant Johnson further stated that the Company was "extremely well positioned for a successful 2003/2004 cough/cold season." During the conference call defendant Hemelt stated that sales:

> [M]ore than doubled for the three months ended September 30 from the third quarter of last year. Sales increased 163% to 13.4 million dollars compared to 5.1 million dollars, last year. Earnings per share on a fully diluted basis for the third quarter increased 29 cents from 11 cent in 2002. The growth in sales was driven by increased sales of all ten of our Zicam products.

Defendant Johnson further stated that "our expectation for the full year is that our revenues will be up in excess of 50% and that earnings, per share for the full year will be in the 25 to 30 cent range." These statements were materially false and misleading as defendants were aware but failed to disclose that Zicam products, which were responsible for the Company's sales growth, posed a material

health risk to consumers, which when disclosed would adversely affect the Company's business.

35. On November 12, 2003, Matrixx filed its quarterly report for the third quarter of 2003 on Form 10-Q with the SEC. The report reiterated the results announced in the October 22, 2003 press release and was signed by defendants Johnson and Hemelt. In a section of the report titled "Risk Factors," the Company purported to warn of the material risk posed by product liability actions that potentially could be filed against the Company, representing that even a single claim, regardless of merit, can have materially negative consequences for the Company:

> ***We may incur significant costs resulting from product liability claims.***
>
> We are subject to significant liability should use or consumption of our products cause injury, illness or death. Although we carry product liability insurance, there can be no assurance that our insurance will be adequate to protect us against product liability claims or that insurance coverage will continue to be available on reasonable terms. A product liability claim, even one without merit or for which we have substantial coverage, could result in significant legal defense costs, thereby increasing our expenses and lowering our earnings. Such a claim, whether or not proven to be valid, could have a

> material adverse effect on our product branding and goodwill, resulting in reducing market acceptance of our products. This in turn could materially adversely affect our results of operations and financial condition.

These statements were materially false and misleading as defendants failed to disclose that a lawsuit alleging that Zicam caused anosmia had already been filed and, given the findings of the researchers at the University of Colorado it was highly likely that additional suits would be filed in the future.

36. In addition, as required by §302 of the Sarbanes-Oxley Act of 2002, the quarterly report contained certifications signed by defendants Johnson and Hemelt representing, among other things, that:

> Based on my knowledge, this report does not contain any untrue statements of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report.

37. On January 7, 2004, Matrixx issued a press release announcing that the Company was revising its guidance for the 2003 year upwards and that it expected its 2003 revenues to grow by 80% from 2002:

> Matrixx Initiatives, Inc. . . . developer and distributor of the expanded line of

> Zicam® Cold Remedy products, today upwardly revised its guidance for fiscal year 2003. The Company expects total 2003 revenues to grow by greater than 80 percent compared to 2002 and fully diluted earnings per share to be in the range of $0.33 to $0.38. In 2002 Matrixx reported net sales of $23.5 million and earnings per share of $0.14 (exclusive of a one-time deferred tax asset accrual). This updates the Company's previous guidance of a 50% increase in revenue and earnings per share of $0.25-$0.30. The increase in the guidance for 2003 reflects a much greater incident of colds than previously anticipated.

38. On February 2, 2004, Matrixx issued a press release which stated:

> All Zicam products are manufactured and marketed according to FDA guidelines for homeopathic medicine. Our primary concern is the health and safety of our customers and the distribution of factual information about our products. Matrixx believes statements alleging that intranasal Zicam products cause anosmia (loss of smell) are completely unfounded and misleading.
>
> In no clinical trial of intranasal zinc gluconate gel products has there been a single report of lost or diminished olfactory function (sense of

> smell). Rather, the safety and efficacy of zinc gluconate for the treatment of symptoms related to the common cold have been well established in two double-blind, placebo-controlled, randomized clinical trials. In fact, in neither study were there any reports of anosmia related to the use of this compound. The overall incidence of adverse events associated with zinc gluconate was extremely low, with no statistically significant difference between the adverse event rates for the treated and placebo subsets.
>
> A multitude of environmental and biologic influences are known to affect the sense of smell. Chief among them is the common cold. As a result, the population most likely to use cold remedy products is already at increased risk of developing anosmia. Other common causes of olfactory dysfunction include age, nasal and sinus infections, head trauma, anatomical obstructions, and environmental irritants.

39. The statements referenced above in ¶¶36-38 were each materially false and misleading because they failed to disclose and misrepresented the following material adverse facts, among others:

(a) by the beginning of the Class Period, a lawsuit had been filed against the Company alleging that the Company's zinc gluconate-based products had caused plaintiffs to

suffer from anosmia and that at least three other similar lawsuits had been filed during the Class Period;

(b) evidence questioning the safety of the Company's mainstay cold medication had surfaced by the beginning of the Class Period and was mounting;

(c) the Company's express assurances that the 10-Q "does not contain any untrue statements of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report" were materially false and misleading because the report omitted any reference to the University of Colorado research, other research linking zinc to loss of smell, the numerous individuals suffering from anosmia after Zicam use, and purported to warn about the harm that ***potential*** product liability lawsuits posed to Matrixx's business without disclosing that lawsuit(s) had ***already*** been filed;

(d) defendants were aware of but failed to disclose that numerous individuals who had used Zicam suffered anosmia; and

(e) defendants were aware of and actively thwarted the dissemination of scientific research conducted at the University of Colorado linking Zicam to anosmia.

40. On January 30, 2004, after the close of ordinary trading, *Dow Jones Newswires* reported that the Food and Drug Administration "is looking into complaints that an over-the- counter common-cold medicine manufactured by a unit of Matrixx

Initiatives, Inc. (MTXX) may be causing some users to lose their sense of smell," after such allegations were made in at least three lawsuits.

41. The Company's stock declined some following the *Dow Jones* report, falling from $13.55 per share on January 30, 2004 to $11.97 per share on February 2, 2004. The Company, however, seeking to reverse the decline in its stock price, issued the press release on February 2 that represented that "statements alleging that intranasal Zicam products cause anosmia (loss of smell) are completely unfounded and misleading." The Company further represented that "[i]n no clinical trial of intranasal zinc gluconate gel products has there been a single report of lost or diminished olfactory function (sense of smell)." Such statements were materially false and misleading because, as the Company would later admit, no clinical study has examined the relationship between zinc gluconate gel and anosmia and other research had, in fact, shown such a link. The Company's vigorous, but baseless, denials had their intended effect: the stock price rose, closing at $13.40 per share on February 3, 2004.

HEALTH RISKS OF ZICAM ARE COMMUNICATED TO THE PUBLIC

42. On February 6, 2004, *Good Morning America,* a nationally-broadcast morning news program, reported on the connection between Matrixx's zinc gluconate and anosmia. According to reporter John Ferrugia, "Dr. Bruce Jafek has discovered more than a dozen patients with the same troubles as Linda [who claims that Zicam Gel caused her anosmia], after using the Zicam product." With

respect to pending lawsuits, John Ferrugia reported that. "Well, in fact there have been, so far, four lawsuits. Others are being prepared, anywhere from California to Michigan. And so far, Matrixx-Initiatives [sic] has denied that there's any problem, saying that there is no liability. They're saying there's a lot of different reasons you can lose your sense of smell and Zicam isn't one of them."

43. In response to the *Good Morning America* segment disclosing Dr. Jafek's findings linking Zicam to anosmia, the price of Matrixx common stock plummeted, falling from $13.05 per share on February 5, 2004, to close at $9.94 per share on February 6 — a one-day drop of 23.8% on unusually heavy trading volume.

44. On February 6, 2004, Matrixx issued a press release "Reaffirm[ing] Safety of Intranasal Zicam(R) Remedy," reiterating its position that the product is safe and that no clinical trial has shown a connection between its product and anosmia:

> We want to assure our consumers that Zicam Cold Remedy intranasal zinc gluconate products are manufactured and marketed according to Food and Drug Administration guidelines for homeopathic medicine. Our primary concerns are the health and safety of those who use Zicam Cold Remedy nasal gels and the distribution of factual information about our products.
>
> In no clinical trial of intranasal zinc gluconate gel products has there been a single report of lost or

> diminished olfactory function (sense of smell). Rather, the safety and efficacy of zinc gluconate for the treatment of symptoms related to the common cold have been well established in two double-blind, placebo-controlled, randomized clinical trials. In fact, in neither study were there any reports of anosmia related to the use of this compound. The overall incidence of adverse events associated with zinc gluconate was extremely low, with no statistically significant difference between the adverse event rates for the treated and placebo subsets.

45. However, on February 19, 2004, defendants filed an 8-K with the SEC which stated that the Company had

> convened a two-day meeting of physicians and scientists to review current information on smell disorders. The meeting was held in response to a poster presentation at the American Rhinological Society in September 2003 alleging an association between the use of Zicam and the onset of smell disorders.

46. The February 19, 2004, 8-K further stated that: "In the opinion of the panel, there is insufficient scientific evidence at this time to determine if zinc gluconate, when used as recommended, affects a person's ability to smell."

47. On March 4, 2004, reporter John Ferrugia, who had reported on the matter on the

Good Morning America segment, reported, on news website *TheDenverChannel.com* (an affiliate of ABC News), that "Zicam Admits No Studies Done on Loss of Smell." According to the article, "[t]he makers of the nationally advertised cold remedy Zicam now admit that they don't know if their nasal gel could cause loss of smell." A related part of the article reported as follows:

> The stunning information came after a 7NEWS investigation found that some consumers who have used Zicam report the loss of smell.
>
> The company that makes Zicam (pictured left), Matrixx Initiatives, first told us its studies showed the product [was] safe, but it will now begin animal and human testing to determine whether its zinc compound could be harmful when sprayed in the nose, causing some to lose their sense of smell.
>
> These studies come after our investigative report aired both on "7NEWS" and ABC's "Good Morning America." Those reports prompted dozens of complaints to the U.S. Food and Drug Administration, which is now investigating.
>
> Doctors at the University of Colorado Taste and Smell Clinic have an increasing number of patients who say they lost their sense of smell after using Zicam intranasal gel, which contains zinc gluconate.

In turn, the company is taking action.

Dr. Bruce Jafek has been documenting the cases from around the country, and there have been several lawsuits in at least five states. All along, Matrixx Initiatives, the maker of Zicam, said the product was safe. But now it admits there are no studies dealing with the issue.

In a filing to the Securities and Exchange Commission on issues affecting stockholders, Matrixx now discloses:

"There is insufficient evidence at this time to determine if zinc gluconate, when used as recommended, affects a person's ability to smell."

What's more, after our initial investigation, dozens of consumers have filed complaints with the Food and Drug Administration.

In response, the company formed a medical advisory panel in February.

It says it will now conduct: "... animal and human studies to further characterize these post-marketing complaints." Study findings are expected to be available in 12 months.

"It seems to me that those studies should have been done before

they put the product on the market," said Jafek.

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scientific panel or at least put a warning label so people can be aware of this problem," said Jafek. "If you want to use this product to possibly shorten duration or severity of your cold, do so but be aware that it may cause a loss of smell."

Zicam makes many products, including lozenges. These are not at issue — only the nasal spray that contains zinc gluconate. A representative for the company responded to our story and said that Matrixx believes the product is safe and does not cause loss of smell, even though the company admits there are no studies to prove it. Even so, the company says it will not remove the nasal spray from the shelves and has no plans to put a caution label on it.

A company representative says consumers can make their own decision until studies are finished.

48. The Company's annual report, filed with the SEC on Form 10-K on March 19, 2004, stated that numerous suits alleging that its Zicam product(s) caused anosmia had been filed, including one brought in the Superior Court of Maricopa County, Arizona, on behalf of 64 plaintiffs:

> Products Liability Matters
>
> Litigation relating to Zicam® Cold Remedy nasal gel arises from claims that the product causes the permanent loss of taste and smell, or anosmia. The Company feels that the clinical studies performed on the product are sufficient evidence to refute such claims.
>
> As of December 31, 2003, suits involving three users of the Zicam® Cold Remedy nasal gel products had been filed in various federal and state courts. All of these suits are at a preliminary stage and the Company has not yet obtained and reviewed complete information regarding the Plaintiffs and their medical conditions, and consequently, the Company is unable to fully evaluate the claims.
>
> On March 12, 2004, the Company was served with a complaint that was filed in the Superior Court of Maricopa County, Arizona, whereby sixty-four Plaintiffs alleged that the use of the Zicam® Cold Remedy nasal gel products resulted in anosmia, the loss of their sense of smell. Specific

damages have not been requested and the Company has turned the lawsuit over to its product liability insurance carrier.

The Company is actively engaged in defending these various lawsuits.

49. According to Matrixx's own SEC filings, from late 2003 through October 2004 Matrixx has been sued by approximately 284 individuals in 19 different lawsuits alleging that Zicam caused damage to their sense of smell. Plaintiff has identified the following personal injury lawsuits which are detailed in the following table:

CASE	CASE NO.	DATE FILED	JURISDICTION	NO. OF PLAINT-IFFS
Christensen, et al v. Matrixx Initiatives, Inc., et al.	4:03-cv-0146-HWB	10/14/03	United States District Court, Western District of Michigan (Kalamazoo)	2
Nelson v. Matrixx Initiatives, Inc., et al.	YC048136	12/08/03	Los Angeles Superior Court	1
Sutherland v. Matrixx Initiative, Inc., et al.	CV2003-1635-WHR	12/18/03	Circuit Court of Etowah, Alabama; Removed to Northern District of Alabama (Middle): 4:2004cv00129	1

Bentley, et al v. Matrixx Initiatives, Inc., et al.	CV2004-001338	01/23/04	Superior Court of Arizona (Maricopa County)	5 (266 consolidated)
Ringbauer, et al. v. Matrixx Initiatives, Inc., et al.	CV2004-002822	02/11/04	Superior Court of Arizona (Maricopa County); Removed to District of Arizona (Pheonix): 04-CV-513	1
Abramsen, et al v. Matrixx Initiatives, Inc,. et al.	CV2004-04415	03/05/04	Superior Court of Arizona (Maricopa County) Consolidated into Bentley on 09/22/04	64
Powell, et al. v. Matrixx Initiatives, Inc., et al.	CV2004-006062	03/29/04	Superior Court of the State of Arizona (Maricopa County)	3
Kalfian v. Matrixx Initiatives, et al.	04-CV-119	04/07/04	United States District Court for the District of Rhode Island (Providence)	1
Hood v. Matrixx Initiatives, Inc., et al.	CACE04006193	04/14/04	Broward County 17th Judicial Circuit of Florida	2

Benkwith v. Matrixx Initiatives, Inc., et al.	CVO4-1180 (CNP)	05/03/04	Circuit Court for Montgomery County, Alabama; Removed to Middle District of Alabama (Montgomery): 2:04-cv-00623-MEF-DRB	1
Doullard v. Matrixx Initiatives, Inc., et al.	CV2004-008950	05/06/04	Superior Court of the State of Arizona (Maricopa County); Consolidated into Bentley on 09/22/04	1
Mayo v. Matrixx Initiatives, Inc., et al.	ESX-L-3551-04	05/06/04	Superior Court of New Jersey (Essex County); Removed to District of New Jersey (Newark): 2:04-cv-03197-WJM-RJH	1
Adams, et al. v. Matrixx Initiatives, Inc., et al.	CV2004-008929	05/07/04	Superior Court of the State of Arizona (Maricopa County); Consolidated into Bentley on 09/22/04	89

Lutche v. Matrixx Initiatives, Inc., et al.	CV2004-008704	05/07/04	Superior Court of the State of Arizona (Maricopa County); Consolidated into Bentley on 09/22/04	1
Hunter, et al v. Matrixx Initiatives, Inc., et al.	CV2004-010830	06/04/04	Superior Court of the State of Arizona (Maricopa County), Consolidated into Bentley on 09/22/04	8
Bryant v Matrixx Initiatives, Inc., et al.	04CV808	06/14/04	District Court, Boulder County, Colorado; Removed to District of Colorado (Denver); 1:04-cv-02317-MSK-BNB	1
Wyatt v. Matrixx Initiatives, Inc., et al.	2.04-cv-04-1230-UWC	06/15/04	United States District Court, Northern District of Alabama	1
Hilton v. Matrixx Initiathes, Inc., et al.	04 82061620 04	06/27/04	48th Judicial District Court, Tarrant County, Texas; Removed to Northern District of Texas: 4:04-cv-00519	1

Akers, et al. v. Matrixx Initiatives, Inc., et al	CV2004-016010	08/20/04	Superior Court of the State of Arizona (Maricopa County); Consolidated into Bentley on 09/22/04	97
Hans, et al v. Matrixx Initiatives, Inc., et al.	3.04-cv-00540-TBR	09/13/04	United States District Court, Western District of Kentucky (Louisville)	4
Rostron v. Matrixx Initiatives, Inc., et al.	4.04-cv-03136-WMA	11/01/04	United States District Court for Northern District of Alabama	2
Swanbeck v. Matrixx Initiatives, Inc., et al.	L003096-04	11/18/04	Superior Court of the State of New Jersey (Morris County)	1
O'Hanlon, et al. v. Matrixx Initiatives, Inc., et al.	2:04cv10391- AHM-JTL	12/21/04	Central District of California; Removed from Los Angeles County Superior Court, Case No. BC3220239	2
Williams, et al. v. Matrixx Initiatives, Inc., et al.	4:04-cv-03548-UWC	12/29/04	United States District Court for Northern District of Alabama	5
Gillespie v. Matrixx Initiatives, Inc., et al.	8:05-cv-00047	01/13/05	Central District of California, Removed from Orange County Superior Court, Case No. 04CC11976.	1

Bourgeios v. Matrixx Initiatives, Inc. et al.	4.05-cv-00393-RBP	02/22/05	Northern District of Alabama (Middle)	1

FALSE FINANCIAL REPORTING DURING THE CLASS PERIOD

50. In order to inflate the price of Matrixx' s stock, defendants caused the Company to falsely report its results for 3Q of 2003 by failing to disclose, if not reserve for, a potential liability that had surfaced prior to the Class Period arising from health related concerns questioning the safety of its mainstay cold medication in violation of Generally Accepted Accounting Principals ("GAAP").

51. The 3Q 2003 results were included in the 10-Q filed with the SEC on November 12, 2003. The results for quarter ending September 30, 2003 were also included in a press release issued at the start of the Class Period on October 22, 2003. These SEC filings represented that the financial information was a fair statement of the Company's financial results and that the results were prepared in accordance with GAAP.

52. These representations were false and misleading as to the financial information reported, as such financial information was not prepared in conformity with GAAP, nor was the financial information "a fair presentation" of the Company's operations due to the Company's improper accounting for its reserves, causing the financial results to be presented in violation of GAAP and SEC rules.

53. GAAP are those principles recognized by the accounting profession as the conventions, rules and procedures necessary to define accepted accounting practice at a particular time. SEC Regulation S-X (17 C.F.R. §210.4-01(a)(1)) states that financial statements filed with the SEC, which are not prepared in compliance with GAAP are presumed to be misleading and inaccurate, despite footnote or other disclosure. Regulation S-X requires that interim financial statements must also comply with GAAP, with the exception that interim financial statements need not include disclosure which would be duplicative of disclosures accompanying annual financial statements. 17 C.F.R. §210.10- 01(a).

54. GAAP, as set forth in Financial Accounting Standards Board ("FASB") Statement of Financial Accounting Standards ("SFAS") No. 5, Accounting for Contingencies, requires that a loss be accrued whenever it is probable a loss has been incurred or an asset impaired and the amount of the loss can be reasonably estimated. If the loss is at least reasonably possible but no reasonable estimate can be made, the contingency at a minimum should be disclosed. According to SFAS No. 5:

> An estimated loss from a loss contingency . . . shall be accrued by a charge to income if both of the following conditions are met:
>
> a. Information available prior to issuance of the financial statements indicates that it is probable that an asset had been impaired or a liability had been incurred at the date of the financial statements. It is implicit in

this condition that it must be probable that one or more future events will occur confirming the fact of the loss.

b. The amount of loss can be reasonably estimated.

* * *

If no accrual is made for a loss contingency because one or both of the conditions in paragraph 8 are met, or if an exposure to loss exists in excess of the amount accrued pursuant to the provisions of paragraph 8, disclosure of the contingency shall be made when there is at least a reasonable possibility that a loss or an additional loss may have been incurred.[3] The disclosure shall indicate the nature of the contingency and shall give an estimate of the possible loss or range of loss or state that such an estimate cannot be made.

* * *

Obligations other than warranties may arise with respect to products or

---

[3] For example, disclosure shall be made of any loss contingency that meets the condition in ¶8(a) — but that is not accrued because the amount of loss cannot be reasonably estimated (¶8(b)). Disclosure is also required of some loss contingencies that do not meet the condition in(¶8(a) — namely, those contingencies for which there is a reasonable possibility that a loss may have incurred even though information may not indicate that it is probable that an asset had been impaired or a liability had been incurred at the date of the financial statements.

> services that have been sold, for example, claims resulting from injury or damage caused by product defects. If it is probable that claims will arise with respect to products or services that have been sold, accrual for losses may be appropriate. ***The condition in paragraph 8(a) would be met, for instance, with respect to a drug product or toys that have been sold if a health or safety hazard related to these products is discovered and as a result it is considered probable that liabilities have been incurred. The condition in paragraph 8(b) would be met if experience or other information enables the enterprise to make a reasonable estimate of the loss with respect to the drug product or the toys.***

SFAS No. 5 ¶¶8, 10 & 26.

55. Here, at a minimum, by 3Q of 2003, Matrixx should have disclosed, if not provided a reserve for, a potential contingency that had arisen related to safety issues concerning its products. During the Class Period, Matrixx did not disclose that several lawsuits had been filed against the Company, including one prior to the start of the Class Period, alleging that the Company's zinc gluconate-based products had caused plaintiffs to suffer from anosmia and that anecdotal evidence had surfaced questioning the safety of the Company's mainstay cold medication. The failure to disclose these known contingencies violated GAAP.

56. Due to these accounting improprieties, the Company presented its financial results and statements in a manner which violated GAAP, including violation of the following fundamental accounting principles:

(a) the principle that interim financial reporting should be based upon the same accounting principles and practices used to prepare annual financial statements. (APB No. 28, ¶10);

(b) the principle that financial reporting should provide information that is useful to present and potential investors and creditors and other users in making rational investment, credit and similar decisions. (FASB Statement of Concepts No. 1, ¶34);

(c) the principle that financial reporting should provide information about the economic resources of an enterprise, the claims to those resources, and effects of transactions, events and circumstances that change resources and claims to those resources. (FASB Statement of Concepts No. 1, ¶40);

(d) the principle that financial reporting should provide information about how management of an enterprise has discharged its stewardship responsibility to owners (stockholders) for the use of enterprise resources entrusted to it. To the extent that management offers securities of the enterprise to the public, it voluntarily accepts wider responsibilities for accountability to prospective investors and to the public in general. (FASB Statement of Concepts No. 1, ¶50);

(e) the principle that financial reporting should provide information about an

enterprise's financial performance during a period. Investors and creditors often use information about the past to help in assessing the prospects of an enterprise. Thus, although investment and credit decisions reflect investors' expectations about future enterprise performance, those expectations are commonly based at least partly on evaluations of past enterprise performance. (FASB Statement of Concepts No. 1, ¶42);

(f) the principle that financial reporting should be reliable in that it represents what it purports to represent. That information should be reliable as well as relevant, is a notion that is central to accounting. (FASB Statement of Concepts No. 2, 7158- 59);

(g) the principle of completeness, which means that nothing is left out of the information that may be necessary to insure that it validly represents underlying events and conditions. (FASB Statement of Concepts No. 2, ¶79); and

(h) the principle that conservatism be used as a prudent reaction to uncertainty to try4o ensure that uncertainties and risks inherent in business situations are adequately considered. The best way to avoid injury to investors is to try to ensure that what is reported represents what it purports to represent. (FASB Statement of Concepts No. 2, ¶¶95, 97).

57. Further, the undisclosed adverse information concealed by defendants during the Class Period is the type of information which, because of SEC regulations, regulations of the national stock exchanges and customary business practice, is expected by investors and securities

analysts to be disclosed and is known by corporate officials and their legal and financial advisors to be the type of information which is expected to be and must be disclosed.

UNDISCLOSED ADVERSE INFORMATION

58. The market for Matrixx securities was open, well-developed and efficient at all relevant times. As a result of defendants' materially false and misleading statements and failures to disclose adverse information regarding Zicam, Matrixx securities traded at artificially inflated prices during the Class Period. The artificial inflation continued until at least February 6, 2004. Plaintiff and other members of the class purchased or otherwise acquired Matrixx securities relying upon the integrity of the market price of the Company's securities and market information relating to Matrixx and have been damaged thereby.

59. During the Class Period, defendants materially misled the investing public, thereby inflating the price of Matrixx common stock, by publicly issuing false and misleading statements and omitting to disclose material adverse facts regarding Zicam, necessary to make defendants' statements, as set forth herein not false and misleading. Said statements and omissions were materially false and misleading in that they failed to disclose material adverse information regarding Zicam and misrepresented the truth about the Company, its business and operations, as detailed herein.

60. At all relevant times, the material misrepresentations and omissions particularized in this Complaint directly or proximately caused or were a substantial contributing cause of the

damages sustained by plaintiff and other members of the class. As described herein during the Class Period, defendants made or caused to be made a series of materially false or misleading statements about Matrixx's earnings. These material misstatements and omissions created in the market an unrealistically positive assessment of Matrixx and its prospects as operations, thus causing the Company's common stock to be overvalued and artificially inflated at all relevant times. Defendants' materially false and misleading statements during the Class Period resulted in plaintiff and other members of the class purchasing the Company's common stock at artificially inflated prices, thus leading to their losses when the illusion was revealed and the market was able to accurately value the Company.

APPLICABILITY OF PRESUMPTION OF RELIANCE: FRAUD-ON-THE-MARKET DOCTRINE

61. At all relevant times, the market for Matrixx's securities was an efficient market for the following reasons, among others:

(a) Matrixx's stock met the requirements for listing and was listed and actively traded on the NASDAQ National Market, a highly efficient and automated market;

(b) as a regulated issuer, Matrixx filed periodic public reports with the SEC and the NASDAQ National Market;

(c) Matrixx regularly communicated with public investors via established market communication mechanisms, including through regular disseminations of press releases on the

national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and

(d) Matrixx was followed by several securities analysts employed by major brokerage firms who wrote reports which were distributed to the sales force and certain customers of their respective brokerage films. Each of these reports were publicly available and entered the public marketplace.

62. As a result of the foregoing, the market for Matrixx's securities promptly digested current information regarding Matrixx from all publicly available sources and reflected such information in Matrixx's stock price. Under these circumstances, all purchasers of Matrixx's securities during the Class Period suffered similar injury through their purchase of Matrixx's securities at artificially inflated prices and a presumption of reliance applies.

ADDITIONAL SCIENTER ALLEGATIONS

63. As alleged herein, defendants acted with scienter in that defendants knew that the public statements or documents issued or disseminated in the name of the Company were materially false and misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws. As set forth elsewhere herein in detail, defendants, by virtue of their receipt of information reflecting the true facts regarding

Matrixx, their control over, and/or receipt and/or modification of the Company's alleged materially misleading misstatements and/or their associations with the Company which made them privy to confidential proprietary information concerning Matrixx, participated in the fraudulent scheme alleged herein.

64. Defendants were aware since at least September of 2003, that numerous users of their Zicam product had experienced a rare condition known as anosmia or loss of smell. Findings of post treatment anosmia were reported by Dr. Bruce Jafek, Miriam R. Linschoten and Bruce W. Morrow of the University of Colorado School of Medicine, Department of Otolaryngology at a medical conference in September of 2003. At the time, Dr. Jafek had reported 10 cases of anosmia after Zicam use. As of April of 2004, Dr. Jafek had evaluated over 100 such cases. On September 12, 2003, over one month before the start of the Class Period, Matrixx informed Dr. Jafek that "as a legal matter" he did "not have their permission to use their company name or product trademarks" in the poster reporting Dr. Jafek's research. In order to avoid threatened legal action from the Company, Dr. Jafek deleted any reference to Zicam or Matrixx from the poster which he used to present his research at a medical conference. Dr. Jafek's findings that "[z]inc ions are toxic to olfactory epithelium" and that "[r]eports of severe hyposmia with parosmia or anosmia appear to be related to the intranasal use of zinc gluconate [Zicam Cold Remedy]" were later published in the May/June 2004 issue of the *American Journal of Rhinology*.

PLAINTIFF'S CLASS ACTION ALLEGATIONS

65. Plaintiff brings this action as a class action pursuant to Federal Rules of Civil Procedure 23(a) and (b)(3) on behalf of a class, consisting of all those who purchased the securities of Matrixx between October 22, 2003 and February 6, 2004, inclusive, and who were damaged thereby. Excluded from the class are defendants, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which defendants have or had a controlling interest.

66. The members of the class are so numerous that joinder of all members is impracticable. During the Class Period, Matrixx had approximately 9.4 million shares of common stock outstanding, which were actively traded on the NASDAQ National Market. While the exact number of class members is unknown to plaintiff at this time and can only be ascertained through appropriate discovery, plaintiff believes that there are hundreds or thousands of members in the proposed class. Record owners and other members of the class may be identified from records maintained by Matrixx or its transfer agent and may be notified of this action by mail, using a form of notice similar to that customarily used in securities class actions.

67. Plaintiff's claims are typical of the claims of the members of the class as all members of the class are similarly affected by defendants' wrongful conduct in violations of federal law that is complained of herein.

68. Plaintiff will fairly and adequately protect the interests of the members of the class and has retained counsel competent and experienced in class and securities litigation.

69. Common questions of law and fact exist as to all members of the class and predominate over any questions solely affecting individual members of the class. Among the questions of law and fact common to the class are:

(a) whether the federal securities laws were violated by defendants' acts as alleged herein;

(b) whether statements made by defendants to the investing public during the Class Period misrepresented material facts about the business and operations of Matrixx; and

(c) to what extent the members of the class have sustained damages and the proper measure of damages.

70. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

FIRST CLAIM
Violation of §10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder Against All Defendants

71. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

72. During the Class Period, Matrixx and the Individual Defendants carried out a plan, scheme and course of conduct which was intended to and, throughout the Class Period, did: (i) deceive the investing public, including plaintiff and other class members, as alleged herein; (ii) artificially inflate and maintain the market price of Matrixx's securities; and (iii) cause plaintiff and other members of the class to purchase Matrixx's securities at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, defendants took the actions set forth herein.

73. Defendants: (i) employed devices, schemes, and artifices to defraud; (ii) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (iii) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities in an effort to maintain artificially high market prices for Matrixx's securities in violation of the Exchange Act and Rule 10b-5. All defendants are sued either as primary participants in the wrongful and illegal conduct charged herein or as controlling persons as alleged below.

74. Matrixx and the Individual Defendants, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a continuous course of conduct to conceal adverse material information about the business, operations and future prospects of Matrixx as specified herein.

75. These defendants employed devices, schemes and artifices to defraud, while in possession of material adverse non-public information and engaged in acts, practices, and a course of conduct alleged herein in an effort to assure investors of Matrixx's value and performance and continued substantial growth, which included the making of, or the participation in the making of, untrue statements of material facts and omitting to state material facts necessary in order to make the statements made by Matrixx and its business operations and future prospects in light of the circumstances under which they were made, not misleading, as set forth more particularly herein and engaged in transactions, practices and a course of business which operated as a fraud and deceit upon the purchasers of Matrixx's securities during the Class Period.

76. The Individual Defendants' primary liability and controlling person liability, arises from the following facts: (i) the Individual Defendants were high-level executives and/or directors of the Company during the Class Period; (ii) the Individual Defendants were privy to and participated in the creation, development and reporting of the Company's internal budgets, plans, projections and/or reports; and (iii) the Individual Defendants

were aware of the Company's dissemination of information to the investing public which they knew or recklessly disregarded was materially false and misleading.

77. Defendants had actual knowledge of the misrepresentations and omissions of material facts set forth herein, or acted with reckless disregard for the truth in that they failed to ascertain and to disclose such facts, even though such facts were available to them. Such defendants' material misrepresentations and/or omissions were done knowingly or recklessly and for the purpose and effect of concealing Matrixx's operating condition and future business prospects from the investing public and supporting the artificially inflated price of its securities. As demonstrated by defendants' overstatements and misstatements of the Company's business, operations and earnings throughout the Class Period, defendants, if they did not have actual knowledge of the misrepresentations and omissions alleged, were reckless in failing to obtain such knowledge by deliberately refraining from taking those steps necessary to discover whether those statements were false or misleading.

78. As a result of the dissemination of the materially false and misleading information and failure to disclose material facts, as set forth above, the market price of Matrixx's securities were artificially inflated during the Class Period. In ignorance of the fact that market prices of Matrixx's publicly traded securities were artificially inflated and relying directly or indirectly on the false and misleading statements made by defendants, or upon the integrity of the market in which the securities trade, and/or on the absence of material adverse

information that was known to or recklessly disregarded by defendants but not disclosed in public statements by defendants during the Class Period, plaintiff and the other members of the class acquired Matrixx securities during the Class Period at artificially high prices and were damaged thereby.

79. At the time of said misrepresentations and omissions, plaintiff and other members of the class were ignorant of their falsity. Had plaintiff and the other members of the class and the marketplace known of the true financial condition and business prospects of Matrixx, which were not disclosed by defendants, plaintiff and the other members of the class would not have purchased or otherwise acquired their Matrixx securities, or, if they had acquired such securities during the Class Period, they would not have done so at the artificially inflated prices which they paid.

80. By virtue of the foregoing, defendants have violated § 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

81. As a direct and proximate result of defendants' wrongful conduct, plaintiff and the other members of the class suffered damages in connection with their respective purchases and sales of the Company's securities during the Class Period.

SECOND CLAIM
Violation of §20(a) of the Exchange Act Against Defendants Johnson and Hemelt

82. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

83. Defendants Johnson and Hemelt acted as controlling person(s) of Matrixx within the meaning of §20(a) of the Exchange Act as alleged herein. By virtue of their high- level positions and their ownership and contractual rights, participation in, and/or awareness of the Company's operations and/or intimate knowledge of the statements filed by the Company with the SEC and disseminated to the investing public, Johnson and Hemelt had the power to influence and control and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the various statements which plaintiff contends are false and misleading. Defendants Johnson and Hemelt were provided with or had unlimited access to copies of the Company's reports, press releases, public filings and other statements alleged by plaintiff to be misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

84. In particular, defendants Johnson and Hemelt had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, are presumed to have had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein and exercised the same.

85. As set forth above, Matrixx and the Individual Defendants each violated § 10(b) and Rule 10b-5 by their acts and omissions as alleged in the Complaint. By virtue of their position as a controlling person, defendants Johnson and Hemelt are liable pursuant to §20(a) of the Exchange Act. As a direct and proximate result of Matrixx's and the

Individual Defendants' wrongful conduct, plaintiff and other members of the class suffered damages in connection with their purchases of the Company's securities during the Class Period.

86. WHEREAS, plaintiff prays for relief and judgment, as follows:

A. Determining that this action is a proper class action, designating plaintiff as lead plaintiff and certifying plaintiff as a class representative under Rule 23 of the Federal Rules of Civil Procedure and plaintiffs counsel as lead counsel;

B. Awarding compensatory damages in favor of plaintiff and the other class members against all defendants, jointly and severally, for all damages sustained as a result of defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

C. Awarding plaintiff and the class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

D. Such other and further relief as the Court may deem just and proper.

JURY TRIAL DEMANDED

Plaintiff hereby demands a trial by jury.

DATED: March 4, 2005 BONNETT, FAIRBOURN, FRIEDMAN & BALINT P.C.

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APPENDIX D

LONGO DECLARATION IN SUPPORT OF MOTION TO DISMISS AND MOTION TO STRIKE

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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

James V. Siracusano, on Behalf of Himself and All Others Similarly Situated, Plaintiff, v. Matrixx Initiatives, Inc., Carl J. Johnson, William J. Hemelt and Timothy L. Clarot Defendants.	CIV-04-886-PHX-MHM CIV-04-1012-PHX-MHM **(Consolidated)** **DECLARATION OF AMY J. LONGO IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS AND MOTION TO STRIKE**

AMY J. LONGO declares pursuant to 28 U.S.C. § 1746 that:

1. I am a member of the bar of the State of California, and am an attorney with O'Melveny & Myers LLP, counsel for defendants in this action. I submit this declaration on personal knowledge in support of the defendants' motion to dismiss and motion to strike the Consolidated Complaint (the "Complaint").

2. Attached as Exhibits 1-12 are true and correct copies of the following documents, which are referenced in the Complaint in the paragraphs cited:

Exh.	Date	Description	Complaint
1.	9/12/03	Letter from Clarot at Matrixx to Dr. Jafek	4, 29, 64
2.	10/22/03	Matrixx Press Release	32

3.	10/23/03	Audio CD of Analyst Teleconference	33, 34
4.	10/23/03	Transcript of Analyst Teleconference	33, 34
5.	11/12/03	Matrixx Form 10-Q 3Q 2003	35, 51
6.	1/7/04	Matrixx Press Release	37
7.	1/30/04	Dow Jones News Service article	6, 40
8.	2/2/04	Matrixx Press Release	7, 38, 41
9.	2/6/04	Transcript of *Good Morning America* broadcast	8, 29, 42
10.	2/6/04	Matrixx Press Release	9, 44
11.	2/27/04	Matrixx Form 8-K	45, 46
12.	3/19/04	Matrixx 2003 Form 10-K	48

***

I declare under penalty of perjury that the foregoing is true and correct. Executed this 31st day of March, 2005 at Newport Beach, California.

s/Amy J. Longo
Amy J. Longo

COPY sent by mail
this 4th day of April 2005, to:

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s/[illegible signature] _____

APPENDIX D.1

LONGO DECLARATION EX. 1

LETTER FROM MATRIXX TO BRUCE JAFEK, M.D., SEPT. 12, 2003

September 12, 2003

Bruce Jafek, M.D.
Department of Otolaryngology
Head and Neck Surgery
UCHSC (B-250)
4200 East Ninth Avenue
Denver, CO 80262

Re: Presentation at 2003 American Rhinologic Society Meeting

Dear Dr. Jafek:

We recently learned that you and your colleagues may be planning to make a presentation on the subject of anosmia secondary to the use of zinc nasal products at the upcoming ARS meeting.

The safety and efficacy of zinc gluconate for the treatment of symptoms related to the common cold are supported by the results of two double-blind, randomized clinical trials.[1,2] There were no reports of anosmia in the treatment arm of either study. In fact, in both studies, the overall incidence of adverse events associated with zinc gluconate treatment was extremely low, with no statistically significant difference between the adverse event rates for the treated and placebo subsets.

As the manufacturers of Zicam® zinc gluconate nasal products, we are very much interested in learning more about the adverse reports included in

your presentation and, to the extent you have valid clinical data supporting your conclusions, we would appreciate receiving that immediately. Because we highly value our reputation for providing quality healthcare products that are safe, anything that might call that into question is of concern to us.

In our attempt to understand the content of your presentation, we are becoming increasingly concerned that zinc gluconate may be inappropriately linked with adverse reactions associated with zinc sulfate. It is our understanding your presentation references 1936 animal data on the toxic effects of zinc sulfate. This information cannot and should not be extrapolated to the use of intranasal formulations of zinc gluconate.

As I am sure you are aware, the medical literature on anosmia describes a variety of etiologies for this condition, including trauma, viral infection, and aging. Prior to your presentation next week, we would very much appreciate the opportunity to learn more about the reports you will be describing and the basis for linking them with the use of zinc nasal products.

We trust you would not to proceed with a program that does not accurately and fairly portray our company or our products. Additionally we point out that, as a legal matter, you do not have our permission to use our company name or product trademarks.

Sincerely,

s/Timothy L. Clarot
Timothy L. Clarot
Director of Research and Development

cc: James A. Hadley, M.D.
American Rhinologic Society, President Elect
1065 Senator Keating Blvd., Suite 210
Rochester, NY 14618

References:

1. Hirt M, Nobel S, Ernesto B: Zinc nasal gel for the treatment of common cold symptoms: A double-blind, placebo-controlled trial. *ENT J* 2000; 79:778-782.

2. Mossad SB: Effect of zincum gluconicum nasal gel on the duration and symptom severity of the common cold in otherwise healthy adults. *QJM* 2003;96:35-43.

APPENDIX D.2

LONGO DECLARATION EX. 2

MATRIXX PRESS RELEASE, OCT. 22, 2003

[Graphic omitted]

Matrixx Initiatives, Inc. Announces 163% Third Quarter 2003 Net Sales Increase; Q3 Net Income Increases 170%

10/22/2003 7:15 PM ET

PHOENIX, Oct. 22, 2003 / PRNewswire — First Call via COMTEX/--

Matrixx Initiatives, Inc. (Nasdaq: MTXX), developer and distributor of the expanded line of Zicam® products, today announced net sales of $13.4 million for the third quarter of 2003, a 163 percent increase versus $5.1 million in the comparable quarter of 2002. Net income for the quarter was $2.8 million or $0.29 per share, versus $1.0 million, or $0.11 per share for the third quarter of 2002.

Net sales for the nine month period ended September 30, 2003 were $25.3 million, a 111 percent increase over the $12.0 million reported for the comparable nine month period last year. Net income for the first nine months of this year increased 114 percent to $2.3 million, or $0.25 per share, compared to $1.1 million, or $0.11 per share, for the comparable period last year.

Carl J. Johnson, president and chief executive officer of Matrixx Initiatives, said, 'The financial results for the third quarter and nine month period are clear indications that the execution of our strategic business plan has continued on track. We are solidly profitable and cash flow positive while having made

substantial investments in advertising, marketing and research and development. These targeted investments are translating into expanded brand awareness and product acceptance by an increasingly sophisticated consumer market. We are very pleased with our results.'

Highlights for the quarter included:

-- Matrixx updated its financial guidance and now expects full-year 2003 earnings per share of $0.25 to $0.30 on a diluted basis.

-- The Company commenced nationwide shipment to retail customers of three unique new oral delivery forms of the Zicam Cold Remedy product line: Zicam Cold Remedy Oral Mist™, Zicam Cold Remedy Chewables™, and Zicam Cold Remedy RapidMelts™.

-- The Company settled litigation with its current swab product manufacturer on August 13, 2003 resolving all disputed issues. The current swab manufacturer has agreed to extend the manufacturing contract through the first quarter of 2004 and to maintain swab production at current levels.

-- The Company announced its intention to launch a new, improved, consumer-preferred swab design in the first quarter of 2004 for its popular Zicam Cold Remedy Swabs and Zicam Kids Size Cold Remedy Swabs with the expectation of improved gross margins compared to the current swab product, as well as avoidance of the supply issues faced during 2002 and 2003.

-- Matrixx secured a two-year extension of its $2.5 million credit facility with Comerica Bank

securing a substantial improvement in the Company's borrowing ability, as well as a reduction in its borrowing rate. The Company currently has no outstanding borrowings under the credit facility.

-- Retail stores results (three-outlet syndicated scanner data; excluding the largest mass merchant) reflect continued growth in the Zicam brand's retail-sales volume, which increased 89 percent in the last 52 weeks ended September 7, 2003, versus the comparable period a year ago. These results include a more than 90percent increase in retail sales for Zicam Cold Remedy nasal gel in various forms, indicating continued growth of consumer demand for the Company's cold remedy formula.

Mr. Johnson continued, "The Zicam brand is poised for growth in the upcoming co [omission in the original]

Consolidated Financial Results

William Hemelt, executive vice president and chief financial officer, stated, 'Durin [omission in the original]

Third-Quarter 2003 Consolidated Financial Results ($000s)

	2003 3rd Qtr	2002 3rd Qtr	Nine Months Ended Sept. 30, 2003	Nine Months Ended Sept. 30, 2002
Net Sales	$13,374	$5,079	$25,270	$11,971
Cost of Sales	4,215	1,668	8,010	3,440
Gross Profit	9,159	3,411	17,260	8,531

Operating Expenses	3,756	2,525	11,620	7,624
Research and Development	795	150	1,702	272
Income from Operations	4,608	736	3,938	635
Total Other Income (expense)	1	48	(77)	121
Net Income Before Tax	4,609	784	3,861	756
Income Tax Expense (benefit)	1,846	(239)	1,548	(324)
Net Income from Continuing Operations	$2,763	$1,023	$2,313	$1,080
Net Income Per Share	$0.29	$0.11	$0.25	$0.11
Average Shares Outstanding (mil)	9.4	9.4	9.4	9.4

Selected Balance Sheet Information ($000s)	Sept. 30, 2003	Dec. 31, 2002	Sept. 30, 2002
Cash and Marketable Securities	$6,613	$12,010	$12,358
Working Capital	$14,912	$10,189	$11,236
Total Assets	$44,981	$47,185	$35,601
Total Debt	$2,720	$5,254	$7,889
Shareholders' Equity	$37,330	$35,155	$25,443

Matrixx has scheduled a conference call to discuss its financial results at 11:00 a [omission in the original].

About Matrixx Initiatives, Inc.

Matrixx Initiatives, Inc. is engaged in the development, manufacture and marketi [omission in the original] product was shown to reduce significantly the duration of the common cold. The [omission in the original] Matrixx products, go to www.zicam.com. To find out more about Matrixx Initiativ [omission in the original].

Matrixx Initiatives, Inc. Forward Looking Statement Disclaimer:

This news release contains forward looking statements within the meaning of the [omission in the original] expectations and are subject to a number of risks and uncertainties, many of which [omission in the original] that consumer acceptance of the new products will be less than anticipated, the [omission in the original].

SOURCE Matrixx Initiatives, Inc.

William Hemelt, Chief Financial Officer, whemelt@matrixx.com or Lynn Romero, Investor Relations, lromero@matrixxinc.com, both of Matrixx Initiatives, Inc., +1-602-387-5353

http://www.zicam.com

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News Release Index

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APPENDIX D.3

LONGO DECLARATION EX. 4

TRANSCRIPT OF ANALYST TELECONFERENCE, OCT. 23, 2003

Narrator: Good morning and welcome to the Matrixx Initiatives Inc.'s Third Quarter Earnings Conference Call. At this time, all participants have been placed on a listen-only mode, and the floor will be open for questions following the presentation. It is now my pleasure to introduce your host for today's call, Mr. Carl J. Johnson, President and CEO of Matrixx Initiatives Incorporated with guest speaker, Mr. William Hemelt, CFO. Sirs, you may begin.

Carl: Thank you Mary. Good morning everyone. We welcome you to our quarterly earnings call, and I thank you for taking the time to join us. Obviously, at the outset, I have to remind you that during this call, we may make some forward-looking comments and I encourage all of you to read in detail our 10-Q when it comes out and previous 10-Ks about the company. That kind of disclaimer is somewhat difficult to give and to mask my enthusiasm for the most recently completed quarter, as we announced yesterday, sales in the third quarter were up 163% versus last year, income up 170% from last year. Perhaps even more encouraging is the fact that, year-

to-date, our sales are up 111%, our income up 114%, and the fact that in the first nine months of this year we have surpassed our revenue and income for all of 2002. So we are extremely pleased with these results and optimistic about the future. I think the most important elements driving the success that we've recently experienced, is the success of the business plan which we put in place and outlined for our shareholders in the middle of last year as well as the efficiency of the business model that we have built here. Of equal if not greater importance to the factory shipment results that we have experienced are the retail results that we are seeing according to syndicated scanner data that is coming in. Those retail results through October suggest that retail sales on a three outlet basis in the United States, excluding the largest retailer, the largest mass merchant retailer, are up 95% for the latest 52 weeks versus the prior 52 week period. And I can tell you that results at the largest retailer in the country are at or above those levels. So we are extremely encouraged that at this point in time we have very strong momentum going into the upcoming cough and cold season. In addition, what lies behind these results is a unique product in the Zicam product line, a product that offers a unique benefit, the ability for consumers to

actually reduce the duration and severity of the common cold, not just mask the symptoms, and tremendous support that we are receiving from our retail customers. I'm especially gratified with the kind of support we have received from retailers in purchasing our new products during the third quarter of this past year. There are several other important developments that have taken place in the third quarter that deserve mention. First and foremost, the addition of three additional products to our products line, giving us 10 products as of August of this year. Those three new products were all oral delivery products and were developed to enable us to have a much broader appeal amongst consumers. We know from research we've done, approximately 50% of the population is reluctant to use products that are delivered nasally. We saw an opportunity to bring more people into the Zicam franchise by giving them a unique delivery system that could be delivered orally. And we have done that with our oral mist, our chewable product and rapid melt products. It's also important to note that we have, during the third quarter, been able to resolve the swab issue, which was a source of great frustration for us in the last cough/cold season and while there has been some cost associated with resolving that issue, we believe that

cost is well worth it, given the ability to assure ourselves a better service to our customers as we get ready for this cough and cold season. It also gives us the opportunity to move away from what, was obvious to us, was a very undesirable supplier and to introduce to the consumer early next year an improved design for a swab product that consumer research tells us they like even better. And of course, importantly, a product that will have a better cost structure and contribute to improved gross margins in the next year. We also completed a two year extension on our credit facility, which is not in use, but it does improve our borrowing ability should we need it, a borrowing ability that would be at an even lower rate. The third quarter is really the set up quarter for the upcoming cough and cold season and at this point we believe we are extremely well positioned for a successful 2003/2004 cough/cold season, which we're just into the third week of, since that season runs from October through March. But I think it is important to remember that, as we enter the cough/cold season, we enter a period of intense marketing investment for the company. The strong results that we've experienced year-to-date and in the third quarter, also allow us to continue our product development programs as we work to strengthen our product

pipeline to enable us to bring additional new products to the market in the future. With that introduction, I'd like to turn it over to Bill, our CFO, who will comment on the actual financial results.

Bill: Good morning. Sales and earnings, as Carl mentioned, more than doubled for the three months ended September 30th from the third quarter of last year. Sales increased 163% to $13.4 million, compared to $5.1 million last year. Earnings per share on a fully-diluted basis for the third quarter, increased to 29¢ from 11¢ in 2002. The growth and sales was driven by increased sales of all 10 of our Zicam products. Approximately 1/3 of the increase was attributable to the sales with three new Zicam oral cold remedy products that we began shipping in the quarter. The remainder of the sales increase, or roughly 2/3 of the total, was due to increased sales of our other seven Zicam products. Together, these seven Zicam products grew a combined 87% rate above the third quarter of 2002. The gross margin on our products also improved from the third quarter of 2002 from 67% to 68.5%. This improvement reflects the positive impact on gross margin from the three new products as reductions in costs of our existing non-swab products. Negatively impacting our gross margin in the quarter is the

higher cost of the swab products. As Carl mentioned, we will be introducing a new, improved, swab product in the first quarter of 2004 that should allow us to reestablish a higher margin on that product next year. Operating expenses increased more than $1.2 million from the third quarter of 2002 due primarily to the partial accrual of year-end compensation incentive this year which were fully accrued in the fourth quarter of 2002. In addition, higher sales commission expense on the higher sales dollars, impacted operating expense. Also, as Carl mentioned, our R&D expense continues to increase and that's reflected in this quarter and that's consistent with our commitment to expand our R&D efforts to ensure continued product development. On the year-to-date basis, for the nine months ended September 30th, our sales increased to $25.3 million and we reported earnings per share on a diluted basis of 25¢. These numbers not only are greater than what was recorded for the first nine months of 2002, but are greater than what we recorded for all of 2002. Our balance sheet continues to strengthen, which is reflected in the higher working capital and reduced debt of the company since year-end. Though our cash position is down from the year-end level, our accounts receivable position is high due to the large sales we've reported. The

accounts receivable are converting into cash receipts daily, such that our current cash position today is greater than $8,000,000 or more than $1.5 million above the quarter year-end amount. These cash receipts together with future sales, will provide more than sufficient cash to fund our advertising program and enable us to pay off our remaining debt by the end of November. We expect to be debt free at year-end and expect to have $7-8 million of cash on hand at that time. Now I'll turn it back to Carl for some concluding remarks before we take questions.

Carl: Thanks Bill. Let me just, as I begin these concluding remarks, reiterate the guidance that we provided in upgrades just recently. Our expectation for the full year is that our revenues will be up in excess of 50% and that earnings per share for the full year will be in the 25-30¢ range. Again, it's important to bear in mind, that as we enter the fourth quarter of the year, we enter a period of intense marketing support for the product as we continue to build consumer awareness for the Zicam brand and attract new users to the unique benefits that these products offer. Obviously, I am extremely pleased and excited about these results. We had the opportunity to meet with our full board of directors earlier this

week. The board is enthusiastic about what they see here and confident that we can continue to profitably build the Zicam franchise. It's important that I take this time to thank everyone that's involved with this. Employees that we have here at Matrixx and also the many business associates we have across the country, especially our sales organization, the Emerson Group, that's done just an outstanding job in my opinion, of helping us launch the three new oral care products this year as well as continue to build the retail distribution on items we entered last year as well as working very closely with our retail customers to provide strong off-shelf promotional and display support going into the upcoming cough and cold season. I also want to thank the many people that have learned about Matrixx in the past quarter and see this as a unique investment opportunity. I believe that we're very well positioned for continued growth in the future. Obviously we will be faced with challenges, but we remain very optimistic at this time. We intend to stay focused on our mission and to remain professional in the approach that we take to managing this business which should lead, and will lead in my opinion, to a continued increase in shareholder value, which is the real reason that we exist. With those comments, Mary, I would be more than

happy to turn it over to you and accept questions from our listeners.

Mary: Thank you Mr. Johnson. The floor is now open for questions. If you have a question, please press 14 on your touch tone telephone at this time. If at any point your question has been answered, you may remove yourself from queue by pressing the pound key. Questions will be taken in the order they are received. If you do ask a question, while posing your question, please pick up your handset to ensure proper sound quality. Please hold on the line while we poll for questions. Our first question is coming from David Thompson of Matador Funds. Sir, your line is live.

Thompson: Yes, thank you. Question. The coupon I saw in the *Washington Post* -- some coupons for $2 off – how does that work with respect to the income statement, the balance sheet?

Bill: The coupon expense is a deduction from revenues. The one that you probably saw in the paper was probably a store promotion. That is deducted from revenues.

Thompson: Ok. Do they return that to you? But what's the timeframe and how does that hit your revenues and income statement? Could you speak as to how large the programs are?

Bill: Well, I mean, depending upon the retailer, they give us almost immediate

information as to the redemption rates on those. When we book the sale at the time we have those promotion programs, we book an estimate based on our experience as to what the expected redemption will be.

Thompson: So this isn't a new program for you?

Carl or Bill: No it isn't. We've done promotions with retailers. We've also done two national, what are called FSI coupons. We'll be running another one of those in November, next month. That will be in your Sunday supplement to your paper.

Thompson: Very good. Ok. And this accounts receivable. How much were they at quarter end?

Bill: They were approximately $9 million.

Thompson: And AP, accounts payable?

Bill: About $7 million.

Thompson: Great. And the allowance for doubtful accounts?

Bill: Approximately a half million dollars.

Thompson: Great. And, then the inventory you were holding and I think that will be it?

Bill: It's about three and a half million.

Thompson: Three and a half, ok. And I'm sorry, last question and then I'll let you go. This manufacturing, who will actually manufacture the new swab product?

Carl: We don't really release the names of the specific manufacturers that

manufacture our product. There is a contract agreement with outsiders. It is a domestic source. It is a source that meets all CG&P requirements and is an FDA inspected facility.

Thompson: Ok, thank you.

Mary: Our next question is coming from Mark Robins of the Robins Group.

Mark: Hey, congratulations folks. Very good quarter. Help me understand something. First of all, let's talk about the swab expense. Does that get charged off in the quarter and where did that fall?

Bill: When you say the swab expense, I assume you're referring to the higher swab, the premium that we agreed to pay to our supplier, that was reflected in the cost of goods related to the swabs that were sold in the period.

Mark: Ok, I thought there was a settlement and some other fallout from those.

Bill: Well, that was reflected in our second quarter numbers. For the second quarter, we reflected, there were some fines from retailers that were reflected in the second quarter. In addition, we had to reflect the higher cost of swabs that were sold in the second quarter.

Mark: Gotcha. Alright, so that's where the catch up was.

Bill: Yes.

Mark: Ok. Then help me understand, in the past, you've had an increase in your advertising and promotion, but despite that, you've typically had fairly strong fourth quarter in sales, and a fairly strong fourth quarter in revenues. I mean, I know that the sell-in in the Q-3 is pretty substantial. But in the past, they sell through in Q4 and Q1 have always been very good as well. I don't want to get too detailed. I know that's difficult, but your guidance kind of tends to lead us to believe that that may not be the case this year around.

Carl: I don't know that that's the case, Mark. I mean, we're talking about a revenue gain in excess of 50% for the year. You have to bear in mind that when we enter the fourth quarter of this year, we are coming up against a fairly strong year ago quarter. We also, we can never predict what the cold season is going to be like. That's just something that has to play out, that Mother Nature is going to determine what the incidence of colds will be. We also, while we will invest heavily, it's always difficult to tell exactly what the sell through is going to be as you enter that cough/cold season. While we've had an excellent sell-in and distribution build for our new items, we don't yet have any indication what kind of consumer purchase rate we're going to receive on

those new items, and more importantly, what the repurchase rate will be.

Mark: Ok. Alright. Let me get back into queue for awhile.

Bill: Ok.

Mary: Thank you. Our next question is coming from Walter Ramsley of Walrus Partners.

Walter: Hey, congratulations Carl and Bill. That's a tremendous quarter.

Bill: Thank you Walter.

Walter: Tremendous year coming up. Just a couple of things. Kind of following up on that last question. Do you just have kind of a ballpark number for what you think the fourth quarter revenues would, and what you'd have to do to get the earnings guidance that you've put up?

Carl or Bill: I'm sorry. That broke up a little bit on our end Walter. If you could?

Walter: I'm sorry, I didn't say that very well. The fourth quarter revenue, what do you think the company needs to generate to produce the 25-30¢ for the year?

Bill: You know, we haven't been that specific, Walter, with regard to the tying that revenue guidance into that earnings. Let me add, that it's important to note that in the fourth quarter last year, we had a very strong

quarter revenue-wise. We only earned, however, when you take out that deferred tax accrual that we booked then, 3¢ and we invest very heavily in the fourth quarter. I'm not sure that answers your question, but I'm not going to give a specific revenue number that produces the earnings in the fourth quarter.

Walter: Ok, it's just last year you had a pretty big number there, $11.6 million. I'm wondering if that...

Bill: I mean, I think it's fair to assume that we're going to do better than $11.6 million in the fourth quarter.

Walter: All I need to know. Thanks.

Mary: Thank you. Our next question is coming from David Levine of Edgewater Research Partners. Sir, your line is live.

David: Hey guys.

Carl or Bill: Hi David.

David: Stunning.

Carl or Bill: Thank you.

David: I'm sorry Bill. Could you just go through the break down of the revenues related to each product? I think you gave a little break down of that. It kind of zipped by me.

Bill: Yeah. We don't give specifics on each product. What I did say, that of the increase, a third of the increase was

related to our three new products and the remaining increase, 2/3 of it, was related to our seven existing products that we had entering the year. And that those seven old products grew at a combined rate of 87%.

David: Can you provide any breakdown on the portion of that that was sort of swab-related. I always sort of look at the swab, at least where we're at right now, as kind of a new product just because of the issues in the past. Is there anything you can share with respect to the quarter in terms of what maybe was related to swab products there?

Bill: It was less than half of that subgroup, the 2/3. It was less than half, I mean. We're experiencing continued growth in our cold products, our allergy products, our extreme and sinus and moisturizer as well.

David: Ok. Is there going to be some additional accrual for the bonus issues. You said that there was some kind of that accrual in the third quarter. Some of that going to be in the fourth quarter?

Bill: I mean, we accrue basically 3/4 of it in the third quarter. The point is that last year we accrued all of it in the fourth quarter.

David: Ok. So 3/4 of it was in the third quarter.

Bill: Yes, this year, yes.

David: Ok. Do you know when you're going to file the Q?

Bill: I would guess within two weeks.

David: Ok. Can you take us through just a couple of the major components of the cash flow statement? I'm sort of looking at the cash and trying to reconcile a couple of things. Is there some components in there...

Bill: I'll give you a general breakdown of it. The income, of course, was positive. The deferred tax amount which is an add back now because the tax that we report on the income statement that are non-cash. Offsetting that, we had a higher accounts receivable. You know, balance sheet items.

David: Ok.

Bill: Higher accounts receivable. We also are now carrying higher inventory, primarily because we now have swabs, whereas as year-end we didn't have any swabs in inventory. And also the three new products added to inventory requirements. We also actually paid down accounts payable since the end of the year. Now, of course, those balance sheet items will change as we get to year end and then, of course, as we exit the cold season. By the end of next March, April, May, we'll have very little accounts receivable. If you look at our

second quarter Q, our accounts receivable position is down to almost a million dollars, and as I mentioned earlier, we are in excess of nine million dollars currently.

David: Ok. I guess, one more question. I don't know how much you can really address this, but I guess the one thing that I was a little bit surprised at, not negatively surprised, but just surprised, and I don't know why because we've talked about it. I guess I just didn't know quite what the number would be. But looking at the R&D number, that's getting to be a fairly substantial number. Can you give us any sort of flavor on some of the things that maybe you're doing on the R&D side because, I guess, my sense is that looking at things, as you put money into R&D, don't put it there so that it drops in a hole. Obviously, your trying to create something additional out of the R&D side. Can you give us any sense of what some of that might be?

Carl: Well, first of all, the spending level in R&D, I think, is in line with what we have said all along, and that is an intention to spend approximately 6% of sales for the year in R&D, which tends to be a number that is consistent with other consumer products companies in terms of the amount of investment they make to try to build up their product pipeline and ensure a continued growth

of new products. With regards to what specifically we are working on, at this point in time, it would be inappropriate to comment on specifics for two reasons. One, all of the necessary work that we're doing to secure, to put in place, the necessary intellectual property protections, that is not complete, so we don't want to make any public disclosure. Beyond that, we have on several occasions pointed out, that we want to be an over-the-counter pharmaceutical company and we are today competing in the largest subcategory within over-the-counter products. That being cough, cold and allergy. We see additional opportunities in that segment. Beyond that, when you look at other large segments where we believe there may be unmet consumer needs or better ways to satisfy existing consumer needs, the areas where we have the greatest interest are in analgesics and pain reliefs and in oral care. But beyond that, it would probably be inappropriate at this early date to specifically mention what we're working on.

David: Ok, that's fair enough. And I wasn't implying that that number was out of line. I mean, it was just bigger than I thought because the revenues were a lot bigger than I thought, obviously. So I guess going forward, that number is

likely to be some percentage of revenues and that's sort of regardless of what revenues are, I guess. But I guess one more... It is maybe an adjunct to what you, may be an adjunct to the description you just gave. Can you give us any sense of what the plan is or the strategy is to deal with this cash position? I mean, you have a deferred tax asset there, you've got obviously some strong numbers. It looks as though you're going to wash through some receivables and things and what you're going to end up with is an even more substantial cash position. Can you give us any sense of what the strategy is in terms of dealing with this pile of cash?

Bill: I guess as a CFO a pile of cash is never big enough. But I understand at some point it becomes too large. We're not at the stage yet where I would worry that much about the 7 or 8 million dollars that we currently have. It certainly does provide us some financing flexibility if we wanted to do something – if something came along that made sense. But that is not our principal strategy, as you know.

Carl: David, I just want to thank you for acknowledging that there's a pile of cash there.

David: No problem. I picked right up on that. Thank you, guys.

Narrator: Thank you. Our next question is coming from Marie Mancianelli from Furo Brothers. Your line is live.

Marie: Hi everyone.

David: Hello.

Marie: Hi, can you hear me?

David: Yes.

Marie: Hi. Well, first I'd like to ask what are the level of sales and returns and allowances?

Bill: What is the level of – are you talking about ...

Marie: Sales, returns and allowances.

Bill: The level of sales and returns and allowances is less than what we are currently accruing and reserving for. As we have said in our Qs and Ks, we give the specific percentages on our old product and all of our prior products we're reserving at approximately 3 percent; and our current returns are running less than that.

Marie: Can you give me an exact dollar amount?

Bill: No. I mean we don't break it out in that detail. We do detail the specific reserve accrual. Certainly on the balance sheet. The balance sheet includes the reserve that we have and it is reviewed monthly by me. It is reviewed at least quarterly by our outside auditors, and, of course, has

been audited on a year-end financial statement basis.

Marie: Okay. Now, in your 10K there's a mention of an independent warehouse. Can you explain how that operates with respect to revenue recognition and how much inventory is in that warehouse?

Carl or Bill: We use an independent warehouse that is basically the warehouse that we ship from. We don't report any sales for product going into the warehouse. When we ship from the warehouse to our customers, then it's reported as a sale. The terminology "independent warehouse" merely refers to an outside public warehousing facility. We ourselves do not own a warehouse.

Marie: Okay, great. Thank you. I have one more question, if you can answer. Can you make any comment on the litigation MTXX or its officers are involved in, or whether or not there is any SEC investigation?

David: Can you repeat your question?

Marie: Can you comment on other litigation that MTXX or its officers are involved in?

Carl or Bill: The officers of this company are not involved in any litigation.

Marie: Okay. And there's no SEC investigations of any sort?

Carl or Bill: Not to our knowledge.

Marie: Not to your knowledge. Okay, thank you gentlemen.

Narrator: Okay, and the floor is open for questions. If you do have a question, please press 14 on your touchtone phone at this time. Our next question is coming from Jeff Neal of Bear Stearns. Sir, your line is live.

Jeff: Thank you. Good morning guys, great job. I wanted to seek some clarification on the gross margin comment and Mr. Levine may have asked this question and I may have missed it. In the third quarter of last year there was no excess cost or above-contract cost associated with the Swab product, is that correct?

Carl or Bill: That's correct.

Jeff: Okay, and in your previous announcement you had stated that you would absorb approximately $1.2 million of incremental cost in the third and fourth quarter of this year associated with the product, above what you believe your cost should have been, correct?

Bill: That's correct.

Jeff: How much of that expense was absorbed in the third quarter?

Bill: You know, I didn't do that calculation. I would say a rough approximation would be that it would have been split between the third and the fourth quarters almost equally. It's really

related to the level of sales of Swab products over that 6-month period. So basically you could look at this quarter and assume that we absorbed roughly a half million dollars of higher Swab costs.

Jeff: Okay. My next question relates to the Accounts Receivable figure. Could you just make a general comment on the quality of those accounts receivable – I'd have to believe, given the customer base, that they are extremely high quality receivables.

Bill: Yes they are. I mean, the bulk of them certainly are tied in to the top 10 food drug market retailers in the country.

Jeff: So it's not something that investors should concern themselves with?

Bill: Well – a year ago there was one of those big mass market companies that went into bankruptcy, so yes, I worry about them. There's some of them I don't worry about, like WalMart and Walgreens.

Jeff: Good, well that is your job to worry about those things.

Carl: And we do, you know, I mean we monitor their financial results on a pretty routine and close basis.

Jeff: Bill, similar to the description you gave for the source of sales revenue increases, could you make any similar comments with regards to the

breakdown in the gross margin increase as it was contributed to by those product lines?

Bill: I will tell you that our Swab products are probably much less than 60% at this point on a gross margin basis. But that's offset by our 3 new products that are north of 70% and our cold and allergy products that are approaching 80%. And then it is all blended based on the sales of those particular units, the mix of those units, to that 68% in the third quarter.

Jeff: Okay, and is that – the cold/allergy gross margin specifically, at approximately 80% -- is that a figure that you've experienced historically?

Bill: No, I think it's higher than we have. We have recently moved the production of the cold product and have achieved some cost reductions there.

Jeff: Interesting. Thank you, I think that answers all my questions.

Narrator: Our next question comes from Patrick Workin of Rock House Research.

Carl or Bill: Hi Patrick.

Patrick: Good morning. I'm fairly new to the company. On the 3 new products that we've just started to ship, in general, are all 7 of the Zicam-related products going into most of the big box guys?

Carl: Yeah, I think it's fair to say that if you look at our list of top customers, most of them are stocking, at a minimum, 3 or 4 of the cold remedy products, be it the original or line extensions, some in the, say, top 5, stock all 10 of the various products we sell today.

Patrick: Okay. I'm just trying to get a picture for the shelf space here. Would most of the Zicam products sort of be on the same shelf space, and – you know, this cough/cold category is so huge, but who are you guys next to on the shelf? Who do you see is competing for sales dollars?

Carl: Well, obviously, when our customers ask us for our recommendations we always tell them we want all the products that they buy from us to be grouped together as a family because that will maximize the impact which the Zicam name would have as the consumer goes up and down the shopping aisles. All retailers don't always do that. They are their stores and they have the final say in how things will be placed on the shelf. Usually we're having decent success in getting them to put the products together in what they refer to as their Nasal Products section. The one exception that we tend to run into all the time is our Kids-size Swab product. They will take that and put it into a section devoted to child care products.

We're not always pleased with that because it will tend to make it just one SKU sitting in that section and it's harder to see. But in general we end up in the Nasal Products section and the products that are there, some of them tend to be – you know, other nasal products can tend to be either decongestant products, allergy relief products or the cold products. So it gets to be a mixed bag. It's hard to describe it as a uniform section. Your comment is correct in that for the poor consumer walking through the store the cough/cold/allergy area is kind of a jungle. And we've tried very hard to get retailers to put our products together, that's why we changed all of our packaging graphics a year ago, to try to make these products stand out more and easier to see.

Patrick: Okay, thank you, and I guess I had the wrong number. There were actually 10 SKUs then?

Carl: Well there's a total of 10 products today. Three of those, our extreme decongestant or sinus relief and nasal moisturizer, are not cold remedy products. The other 7 are.

Patrick: Okay. And then on the 7 products, and once again I apologize because I'm fairly new to the company, but do you have any – I'm asking, I guess, about

the proprietary nature – is there a store brand or other name brand?

Carl or Bill: No, and I'm glad you asked that. We have two patents on the Zicam product. Those patents extend to 2018. We have three patents pending, or three continuations. We have twice successfully defended our intellectual property from companies that were endeavoring to put out generic or store brand competition. So we at this time do not face that kind of competitive threat.

Patrick: Okay, then I assume you work with the big guys pretty closely on promotion, and I haven't really dug into that yet, but number one is that true? And then number two if you could tell me what your accounting policies are for recognizing that expense as those promotions and/or advertising is run.

Carl: Yeah, I'll comment on how we work with those customers and I'll let Bill comment on the accounting treatment of that. We use the services of a group called the Emerson Group for sales management and support. The Emerson Group is, they have 8 people in the field assigned to all the major retailers that are out there. We indicated in the past that our top 15 customers represent in excess of 80% of our total sales, and that's consistent with I think what most consumer

product companies experience that sell through food, drug and mass merchandiser channels. The people in the Emerson Group, they all have excellent consumer product sales backgrounds, excellent relationships with the major retailers – WalMart, Walgreens, CVS, Target, Kmart, all your major food outlets – and actually, we begin planning our promotional activity with those customers. The activity that is beginning to take place now, we started planning that with them this past February. So – and I'm sure you're not surprised that major retailers are always working roughly 12 months in advance – the plans that are beginning to be executed now have been worked on and developed for several months. As for the accounting for further promotional activity, I'll let Bill comment on that.

Bill: We accrue or expense the cost of all promotional activities that we engage in with our retailers in the months that those promotions occur. So if they run an ad or if they have a dollar off coupon or a dollar back, or what have you, the cost of that is booked in the month that it is run. And then, of course, there's always a true-up that occurs and to the extent we don't know the specific number we book an estimate.

Patrick: Okay, so you do that even on an interim basis?

Bill: Oh, absolutely. We have to do it on a monthly basis.

Carl: Let me just add one other thing about working with these retailers, because they are obviously very large and sophisticated operations but one of the things that has really been very fortunate for us is the level of support that we have received from them. And that's not because they like us as people, it's because Zicam is a high growth item in their stores. It is a premium-priced product at retail, so they like that when a consumer buys Zicam – it's a big ring for them, adds considerably to their shopping basket, and in addition to that, they are making a profit margin themselves on our product that is higher than the average health and beauty care product – and we're excited about that fact. I mean, we want this to be a win for us and our shareholders, as well as a win for retailers in terms of profitability.

Patrick: Okay, but with respect to that – I mean you say it's a higher margin – I assume that you're talking about perhaps higher margin versus some name brand competition, but I think that's probably hard to argue against the store brands where, you know, on an absolute dollar basis that category is hard to compete with. And I guess I'll circle back to a previous question – as big as the category is from a name brand

standpoint who do you see as your biggest competition with respect to the category? Is it P&G? Who is it that you compete with the most?

Carl: Well I think in terms of name brand competition we are obviously competing with all of the major multinational pharmaceutical companies and Proctor & Gamble. Any company that is out there with a product competing in the cough-cold-allergy market. I think what makes us unique and different from all those, however, is that those products are all offering consumers symptomatic relief. If you take one of those products you may get a good night sleep but when you wake up in the morning you've still got your cold. Whereas if you purchase Zicam and use it according to its labeling and its instructions, we're going to be able to, based on our clinical evidence, reduce the duration and severity of that common cold. I'd also comment just briefly on your comment about generic competition given that I have in my own background some experience with that, and yes, you're correct that the margin on generic competition may be higher, the dollars may not be, depending upon the individual product. And more importantly to the retailer, it's branded products that bring traffic into the store, which is of paramount importance to them.

Patrick: I realize that Carl, and I know your background, but I think your retailers are trying to strike a fine balance in profit dollars and at the same time realizing the importance that the advertising by the name brand guys.

Bill: That's true. They constantly are – and they have interest in building their own equity, and there's nothing wrong with that.

Patrick: Right. Last question on the advertising – are you guys, I assume you're involved in some cooperative programs with some of the retailers, and then once again how easy is it to keep track of and how do you guys account for that?

Carl: We certainly are very much involved in cooperative advertising efforts with customers and we try to, wherever it financially makes sense, participate in programs that they offer. The way it's managed is, again, that's part of what the Emerson Group provides for us in planning our merchandising activities with customers and figuring out exactly which programs we will participate in at what times of the year. As to the accounting for it, again I'll let Bill comment on it.

Bill: Again it's the same way – we accrue the expense in the month that the co-op advertising runs.

Patrick: Okay. Alright, thank you very much for the time.

Narrator: Our next question comes from Art Chandler of Weberesh-Morgan Securities. Sir, your line is live.

Art: Thank you. Good morning guys, terrific. Your efforts are being rewarded. Question on the advertising. Can you make any comments about how much you expect to spend in the 4th quarter?

Carl: Art, we don't break it out by just Q-4. What we comment on is that over the season, which is the 4th quarter and the 1st quarter, we will spend in the $8-10 million dollar range, and we maintain some flexibility around that based really upon how we see the cold season developing – whether its an early season or a late season.

Art: Marvelous. In one of your recent press releases you referred to a 10.2% market share, excluding obviously the largest retailer, but how big – I mean, that seems like a pretty phenomenal amount in such a short period of time for anybody to enter that market. Is that what you consider the $300 million piece of the market?

Carl or Bill: Yeah, that's the nasal products segment.

Art: Okay.

Carl: And that segment – as we said, the total cough/cold/allergy market, everything, liquids and tablets and every conceivable form that's out there is a $3 billion retail market.

Art: Okay. Do you have any expectations of when the next product might be coming out of the R&D effort?

Bill: I think – I'm reluctant to give a specific date on that, Art. I mean, obviously I think we'll be in a better position at the end of the year to answer some of that. Our intention would be, assuming some of our efforts continue to be successful, that in the first half of next year I think we can provide – I'm hopeful that we can provide – more detail and information about the kinds of things that we are working on.

Art: Okay, great, thanks. Keep up the good work.

Narrator: Thank you. Our next question comes from Walter Ramsley of Walrus Partners. Sir, your line is live.

Walter: Oh thanks, just a couple of follow-ups. I think we've covered most of the ground. Of the three new products, is one taking the lead, doing better than the other two?

Carl: I don't think so, Walter – we only have, we have one customer where we're able to look at their scanner data that has all three – we really do not have a lot of

data at this point, it's very early in the season, but what we do see in that one case is that all three are selling at about the same rate. Not one of the three is pulling away as a clear-cut winner. I think the other thing that we can – we do tend to be encouraged. Other retailers that have scanner data that we have access to where we can see one or more of the new products in retail, what we are seeing are patterns of consumer takeaway comparable to the kind of results we saw early on last year for some of the products that we introduced at that time. But I really want to caution that it is far too early to draw any conclusions. We have not seen any data whatsoever that reflects retail movement after the start of advertising, which only began last week. So you're as anxious to know about that, as we are, and unfortunately we all just have to be patient and wait for weeks to go by.

Walter: And so the Swab producer, the new one – is that company definitely on track to begin delivering for the first quarter?

Carl: Yes, we are clearly on track for that. I think the development program has gone extremely well. We are very pleased with the support that the contract manufacturer has provided us. We have seen early prototypes off the actual machinery. In fact we've had prototypes that we've been able to give

to consumers in focus group sessions and let them look at it, comment on it, and that research has confirmed what we conducted earlier this year at an earlier design phase, that the consumers do in fact like the new design ever better.

Walter: The price that they're going to charge, is that approximately the same as what it used to be for the Zicam contract, or are you basically going to start saving that $600,000 per quarter?

Bill: We think that – well wait a minute. The $600,000 was the additional cost that IST, the current supplier, was charging us. That clearly will be gone. To what extent we can achieve something better than the contract as it was originally written – right now we're planning on something slightly better than that. Our hope is that over time it will become even greater than that.

Walter: Okay, that's great. Anybody that you know of who is shipping the product internationally, or is there any international demand at all?

Carl: There are no international sales whatsoever, and, as we've talked about on prior occasions, it's really a function of a very complex regulatory environment outside the United States for this product. That's what is really the biggest impediment to taking advantage of that opportunity.

Walter: And just one last thing as far as the advertising goes – you going to use the same basic theme that you've used in the past? Stopping the cold three times faster? Or do you have some new tag lines in the works?

Carl: No, that's the basic theme of the campaign will be the same, you know, get over your cold three times faster, the utilization of the little visual device that we have, or that we used last year. What will be different is that there will be mention of the three new oral care products at the end of the advertising to make sure consumers are aware of the fact that these new oral care forms are out there and available.

Walter: Sounds great!

Narrator: Our last question comes from Jack Neal of Barrister. Sir, your line is live.

Jack: Thank you. Guys, I just had two follow-up questions. First of all, Carl, could you comment – you've often said that a very important strategic initiative of the company is to build the brand, build brand awareness. And that obviously means investing in R&D, investing in advertising, at the sacrifice of profitability. Have you continued from your vantage point to invest in that brand awareness during the second and third quarter of this year. Is the spinning reflective of that? And if you had to characterize in baseball terms

where you are in that brand building endeavor, what inning are you in?

Carl: I would – it's early in the game. We may only be in the third inning. And I think – your question about do we spend in the second and third quarter, our spending skews heavily to the cold season. You spend and you invest to build that brand awareness when the consumer has the need, and they don't have the need for a cold remedy product in the second and third quarter. That's why the investment skews so heavily to Q4 and Q1. But the basic issue you're talking about, which is brand building, there are few things as difficult as building a new consumer product, consumer franchise. This is – the American consumer is torn between lots of different issues, life is complicated and challenging for them between work and families and the various lifestyles that we have. When you stop and think about it, there are very few new consumer products to come to the market. There are many names that all of us know and recognize but many of them have been there for decades. We're kind of a new phenomenon on the scene, only introduced in 1999. It's a very exciting activity to be involved with for myself and for our board, where we have a lot of consumer products experience, but we are early on in this game. And I mentioned that

we met with the board earlier this week, and the board is, while pleased with the results, they believe and I believe there continues to be additional upside opportunity. But that opportunity can only come with a consistent and concerted effort to build consumer awareness, to build trial and sustain repeat purchase. And that is not an easy thing to do. But we are committed to doing that based upon the results that we see to date, which – the kind of growth that we've got and the ability to generate a profit is satisfying to us, but we do believe there is additional upside opportunity.

Jack: Good. That is very clarifying, and that really leads to the next question, and that is this: I imagine some will want to be critical of the impreciseness that they might perceive in the forecasting of your results, but would it be a correct characterization that the unwillingness if you will, to put a number on the fourth quarter is both driven by the amount of spending that you will do and is really not an issue of whether you sell through on the retail end of the product, but really it's an issue of what subsequent sell in to the retailers is, which is driven strictly by an unpredictable item, the cough and cold season. Correct?

Carl: That's very correct. That's right. You know it's always a difficult thing to say

when you're in this kind of a business. If people don't get sick, we're in trouble. You don't want people to get sick, but if they don't it's going to depress the category. We have no indication yet that that's the situation this year, but it's very early. But it's one of the challenges in this particular business. I mean, we can only ship product when in fact consumers are suffering from a cold and looking for ways to get over it.

Jack: Well as a personal testament I'm on my second day of the cold and I'm starting Zicam today!

Carl or Bill: Well we always encourage everyone to use it at the initial sign, so get it earlier!

Jack: Thank you for your answers.

Carl or Bill: Okay.

Narrator: Mr. Johnson, do you have any closing remark?

Carl: No, I would just thank everyone again for taking the time to join us. I hope everyone can sense the enthusiasm and excitement we have for these results, and the optimism we have for the future. I think we're on a good track, and certainly have every intention of continuing to deliver the same kind of results and work towards building this franchise, and obviously work towards building increased value for our shareholders. So again I thank

everyone and look forward to talking to you next – at the end of next quarter.

Narrator: Thank you, Mr. Johnson. This does conclude today's call. Please disconnect your lines at this time, and have a wonderful ...

APPENDIX D.4

LONGO DECLARATION EX. 5

MATRIXX 10-Q 3Q 2003, NOV. 12, 2003

[Graphic and cover material omitted]

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

Form 10-Q

(Mark One)

[X] Quarterly Report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

For the quarter ended September 30, 2003

or

[ ] Transition Report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

For the transition period from _____ to _____

Commission File number 0-27646

Matrixx Initiatives, Inc.

(Name of registrant as specified in its charter)

Delaware	**87-0482806**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)

2375 East Camelback Road, Suite 500
Phoenix, AZ 85016
(Address of principal executive offices)

(602) 387-5353
(Issuer's telephone number)

Indicate by check mark whether the registrant (1) filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES ☒ NO ☐

Indicate by check mark whether the registrant is an accelerated filer (as defined in Exchange Act Rule 12b-2).
YES ☐ NO ☒

There were 9,415,851 shares of the registrant's common stock, $.001 par value, outstanding as of October 31, 2003.

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MATRIXX INITIATIVES, INC.
FORM 10-Q
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Unless otherwise indicated in this quarterly report, "Matrixx," "us," "we," "our", "the Company" and similar terms refer to Matrixx Initiatives, Inc. and its subsidiaries. "Zicam" is a registered trademark of our subsidiary, Zicam, LLC, and the Matrixx name and logo are trademarks of the Company.

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CAUTIONARY STATEMENT REGARDING

FORWARD-LOOKING STATEMENTS AND RISK FACTORS

Forward-Looking Statements

This Form 10-Q, including documents incorporated herein by reference, contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. The words "believe", "expect", "estimate", "anticipate", "intend", "may", "might", "will", "would", "could", "project" and "predict", or similar words and phrases generally identify forward-looking statements. Forward looking statements contained herein and in documents incorporated by reference herein include, but are not limited to statements regarding:

- our plans to introduce a new, improved swab product in the first quarter of 2004, and our expectation that the new product will result in a decrease in the unit cost of our swab products and allow us to improve our gross margins;
- our expectation that consumers will enthusiastically accept our new swab product and that our change of swab manufacturers will allow us to avoid the production and backlog issues that we faced during 2003 and 2003.
- our expectation regarding increases in sales in future periods of our current and new Zicam products;
- our belief that sales, expense levels and earnings in future periods will be primarily affected by timing and amounts of advertising, research and development expenses, costs of introduction of new products, our success in securing additional

retail distribution, expanding consumer awareness and acceptance of our entire Zicam brand of products;

- our expectation regarding the seasonality of our quarterly sales, and our expectation that future earnings will be impacted by the seasonality and timing of certain expenditures;
- our expectation regarding the growth rates for future sales of products;
- our expectation that expenditures for advertising and research and development will vary by quarter throughout the year, with advertising expenses being heaviest in the first and fourth fiscal quarters and our expectation that future operating expenses will vary largely in relation to the level of advertising expenditures;
- our expectation that we will be able to meet demand for our swab products through the end of 2003;
- our expectation that the cost of goods sold will continue to be affected by the relative mix of products sold and the planned introduction of a new swab product will result in a decrease in the unit cost of our swab products;
- our previously announced commitment to expand our research and development efforts in 2003 to an amount equal to approximately 6% of annual net sales;
- our expectation that our net sales for fiscal 2003 will be at least 50% greater than the $23.5 million in net sales that we recorded for fiscal 2002;
- our expectation that net income for 2003 will be $0.25 to $0.30 per fully diluted share;

- our belief that our settlement with IST will help facilitate an orderly transition to the new swab product that we intend to introduce in early 2004, allowing us to provide appropriate levels of service to our retail customers until the transition is complete;
- our expectation that we will not borrow under our credit facility with Comerica Bank in the immediate future;
- our expectation of continuing profitability in future years;
- our intention to continue outsourcing all of our product manufacturing and packaging for the foreseeable future;
- our intention to evaluate our deferred tax valuation allowance regularly and adjust the amount to reflect our expectation of our ability to realize the tax benefit arising from our tax loss carry-forward on a quarterly basis;
- our belief that our current capital resources and credit line are sufficient to fund the Company for the next 12 months; and
- our belief that moderate interest rate increases will not have a material adverse impact on our results of operations or financial position in the foreseeable future.

We may make additional written or oral forward-looking statements from time to time in filings with the Securities and Exchange Commission or in public news releases. Such additional statements may include, but not be limited to, projections of revenues, income or loss, capital expenditures, acquisitions, plans for future

operations, financing needs or plans, the impact of inflation and plans relating to our products or services, as well as assumptions relating to the foregoing. Forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified. Future events and actual results could differ materially from those set forth in, contemplated by, or underlying our forward-looking statements.

Statements in this Form 10-Q, including those set forth in the sections entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations", and under the subheading below entitled "Risk Factors", describe factors that could contribute to or cause actual results to differ materially from our expectations. Other such factors include (i) less than anticipated demand for our current and future products or a weak cold season, (ii) lack of market acceptance for or uncertainties concerning the efficacy of our current and future products, including our new swab, (iii) difficulties in increasing production or maintaining sufficient inventories to meet unexpectedly high demand in the short term, including our inability to resolve product backlog and product pricing issues and difficulties in establishing adequate manufacturing arrangements for our new swab products, (iv) financial difficulties encountered by one or more of our principal customers, (v) difficulties in obtaining additional capital for marketing, research and development, and other expenses, (vi) oversupply of product inventory to retailers resulting in unsold product returns, and (vii) material litigation involving patent and contractual claims, product liabilities or consumer issues.

· Forward-looking statements contained in this Form 10-Q speak only as of the date of this Form 10-Q or, in the case of any document incorporated by reference, the date of that document. We do not undertake, and we specifically disclaim any obligation, to publicly update or revise any forward-looking statement contained in this Form 10-Q or in any document incorporated herein by reference to reflect changed assumptions, the occurrence of unanticipated events or changes to future operating results over time.

Risk Factors

Our new business focus means we have a limited operating history on which to assess our current and prospective performance

Although we have been in operations for a number of years, the significant change of direction and focus in our business that we made in 2001 by exiting the chewing gum business and refocusing entirely on the development, production and sale of over-the-counter pharmaceutical products presents a limited operating history upon which you may evaluate our current and prospective performance. The possibility of our future success must be considered relative to the problems, challenges, complications and delays frequently encountered in connection with the development and operation of a new business, and the development and marketing of relatively new products such as the Zicam products.

If our Zicam products do not gain widespread market acceptance, our anticipated sales and results of operations will suffer

Although studies have indicated that Zicam Cold Remedy can significantly reduce the duration and

severity of the common cold, we cannot be certain that this product (including our new swab formats) will achieve widespread acceptance by the market. To date, Zicam Allergy Relief has not achieved the market success presently enjoyed by Zicam Cold Remedy. In addition, given their recent introduction in late 2002, our five new Zicam products have not yet reached the level of market recognition achieved by the original Zicam Cold Remedy. While we are working to

increase the market presence of Zicam Allergy Relief and our five new Zicam products, we cannot be certain that demand for these products will grow. It is too soon to determine how the market will respond to the three new Zicam products that we began shipping in the third quarter of 2003 or the new swab products that we plan to begin shipping in the first quarter of 2004. If any unanticipated problem arises concerning the efficacy of Zicam Cold Remedy, Zicam Allergy Relief or any of our other new products, or if any of these products fails to achieve widespread market acceptance for any other reason, our operating results and prospects would be materially adversely affected.

Unanticipated problems associated with product development and commercialization could adversely affect our operating results

Our successful development of existing and new products is subject to the risks of failure and delay inherent in the development and commercialization of products based on innovative technologies. These risks include the possibilities that:

- we may experience unanticipated or otherwise negative research and development results;

- existing or proposed products may be found to be ineffective or unsafe, or may otherwise fail to receive required regulatory clearances or approvals;
- we may find that existing or proposed products, while effective, are uneconomical to commercialize or market;
- we may be unable to produce sufficient product inventories to meet customer demand or may encounter other manufacturing difficulties involving our new products and our new swabs;
- existing or proposed products do not achieve broad market acceptance; or
- proprietary rights held by third parties preclude us from developing or marketing existing or proposed products.

Our inability to develop and commercialize our existing products or any new products on a timely basis and within our financial budgets could have a material adverse effect on our operating results and future prospects.

Our inability to provide scientific proof for product claims may adversely affect our sales

The marketing of certain of our Zicam products involves claims that these products assist in reducing the duration and severity of the common cold (in the case of Zicam Cold Remedy and the related Zicam swab products) and controlling allergy symptoms (in the case of Zicam Allergy Relief). Under the Federal Food and Drug Administration ("FDA") and Federal Trade Commission ("FTC) rules, we are required to obtain scientific data to support any health claims we make concerning our products.

Although we have neither provided nor been requested to provide any scientific data to the FDA in support of claims regarding our Zicam products, we have obtained necessary scientific data to support our product claims. We cannot be certain, however, that the scientific data we have obtained in support of our claims will be deemed acceptable to the FDA or FTC, should either agency request any such data in the future. If the FDA or the FTC requests any supporting information, and we are unable to provide support that is acceptable to the FDA or the FTC, either agency could force us to stop making the claims in question or restrict us from selling the affected products.

FDA and other government regulation may restrict our ability to sell our products

We are subject to various federal, state and local laws and regulations affecting our business. Our Zicam products are subject to regulation by the FDA, including regulations with respect to labeling of products, approval of ingredients in products, claims made regarding the products, and disclosure of product ingredients. If we do not comply with these regulations, the FDA could force us to stop selling the affected products or require us to incur substantial costs in adopting measures to maintain compliance with these regulations. Our advertising claims regarding our products are subject to the jurisdiction of the FTC as well as the FDA. In both cases we are required to obtain scientific data to support any advertising or labeling health claims we make concerning our products, although no pre-clearance or filing is required to be made with either agency. If we are unable to provide the required support for such claims, the FTC may stop

us from making such claims or require us to stop selling the affected products.

We may fail to compete effectively, particularly against larger, more established pharmaceutical and health products companies, causing our business and operating results to suffer

The consumer health products industry is highly competitive. We compete with companies in the United States and abroad that are engaged in the development of both traditional and innovative healthcare products. Many of these companies have much greater financial and technical resources and production and marketing capabilities than we do. As well, many of these companies have already achieved significant product acceptance and brand recognition with respect to products that compete directly with our Zicam products. Our competitors may successfully develop and market superior or less expensive products which could render our Zicam and other future products less valuable or unmarketable.

If we are unable to protect our intellectual property or if we infringe the intellectual property of others, our financial condition and future prospects could be materially harmed

We rely significantly on the protections afforded by patent and trademark registrations that we routinely seek from the U.S. Patent and Trademark Office ("USPTO") and from similar agencies in foreign countries. We cannot be certain that any patent or trademark application that we file will be approved by the USPTO or other foreign agencies. In addition, we cannot be certain that we will be able to successfully defend any trademark, trade name or

patent that we hold against claims from, or use by, competitors or other third parties. No consistent policy has emerged from the USPTO or the courts regarding the breadth of claims allowed or the degree of protection afforded under biotechnology and similar patents. Our future success will depend on our ability to prevent others from infringing on our proprietary rights, as well as our ability to operate without infringing upon the proprietary rights of others. We may be required at times to take legal action to protect our proprietary rights and, despite our best efforts, we may be sued for infringing on the patent rights of others. Patent litigation is costly and, even if we prevail, the cost of such litigation could adversely affect our financial condition. If we do not prevail, in addition to any damages we might have to pay, we could be required to stop the infringing activity or obtain a license. We cannot be certain that any required license would be available to us on acceptable terms, or at all. If we fail to obtain a license, our business might be materially adversely affected. In addition to seeking patent protection, we rely upon a combination of non-disclosure agreements, other contractual restrictions and trade secrecy laws to protect proprietary information. There can be no assurance that these steps will be adequate to prevent misappropriation of our proprietary information or that our competitors will not independently develop technology or trade secrets that compete with our proprietary information.

We may incur significant costs resulting from product liability claims

We are subject to significant liability should use or consumption of our products cause injury, illness or

death. Although we carry product liability insurance, there can be no assurance that our insurance will be adequate to protect us against product liability claims or that insurance coverage will continue to be available on reasonable terms. A product liability claim, even one without merit or for which we have substantial coverage, could result in significant legal defense costs, thereby increasing our expenses and lowering our earnings. Such a claim, whether or not proven to be valid, could have a material adverse effect on our product branding and goodwill, resulting in reduced market acceptance of our products. This in turn could materially adversely affect our results of operations and financial condition.

We do not have manufacturing capabilities of our own

We currently do not have the physical or human resources to independently manufacture our Zicam products or any other products that we may develop. We currently outsource all of our product manufacturing and packaging operations and intend to continue this outsourcing for the foreseeable future. If we are unable to enter into cost-effective or otherwise suitable arrangements for manufacturing of our Zicam products or any other products, or if our third party contractors fail to adequately perform their manufacturing operations (as has occurred to date with our new swab products), our sales and related financial results could be materially adversely affected. If, in the future, we decide to establish our own manufacturing facilities, we will require substantial additional funds and significant additional personnel to undertake such operations. We cannot be certain that such funding or a

sufficient number of such qualified persons will be available for such an undertaking.

We may continue to experience product backlogs

At the end of 2002, we had approximately $1.3 million in backlog of swab orders, which continued at reduced levels until the end of March 2003. We have since increased our inventory of swab products in order to prevent a similar backlog from occurring in the 2003-2004 cold season. We expect our new swab manufacturer to provide products beginning in the first quarter of 2004. However, we cannot be certain that these efforts will be sufficient to prevent a backlog of these swab products from repeating itself in the 2003-2004 cold season or that other product backlogs will not occur in the future. Any such future backlogs will potentially result in higher production costs, higher freight costs to expedite shipment of raw materials and finished goods, fines from certain retailers, cancelled orders and lost opportunity costs. These in turn could materially affect our results of operations and financial condition.

The large number of shares eligible for immediate and future sales may depress the price of our stock

Sales of substantial amounts of our common stock in the open market or the availability of a large number of additional shares for sale could adversely affect the market price of our common stock. Substantially all of our outstanding shares of common stock, as well as the shares underlying vested but as yet unexercised warrants and options, have either been registered for public sale or may be sold under Rule 144 promulgated under the Securities Act of 1933, as amended. Therefore, all of

these shares may be immediately sold by the holders. A substantial increase in sales of our common stock could depress the price of our common stock.

Our board of directors is authorized to issue shares of preferred stock that could have rights superior to our outstanding shares of common stock, and, if issued, could adversely impact the value of our common stock

Our certificate of incorporation permits our board of directors, in its sole discretion, to issue up to 2,000,000 shares of authorized but unissued preferred stock. These shares may be issued by our board without further action by our shareholders, and may include any of the following rights (among others) as our board may determine, which rights may be superior to the rights of our outstanding common stock:

- voting rights, including the right to vote as a class on particular matters;
- preferences as to dividends and liquidation rights;
- conversion rights;
- anti-dilution protections; and
- redemption rights.

Since our board of directors has the authority to determine, from time to time, the terms of our authorized preferred stock, there is no limit on the amount of common stock that could be issuable upon conversion of any future series of preferred stock that may be issued. The rights of holders of our common stock will be subject to, and may be adversely affected by, the rights of the holders of any

series of preferred stock that may be issued in the future. In addition, the market price of our common stock may be adversely affected by the issuance of any series of preferred stock with voting or other rights superior to those of our common stock. The issuance of any series of preferred stock could also have the effect of making it more difficult for a third party to acquire a majority of our outstanding common stock.

The price of our stock may continue to be volatile

The market price of our common stock, which is quoted for trading on the Nasdaq National Market, has been highly volatile and may continue to be volatile in the future. Any or a combination of the following factors could cause the market value of our common stock to decline quickly: Operating results that differ from market expectations, negative or other unanticipated results of clinical trials or other testing, delays in product development, technological innovations or commercial product introductions by our competitors, changes in government regulations, developments concerning proprietary rights, including pending or threatened patent litigation, public concerns regarding the safety of any of our products and general economic and stock market conditions. Since the Spring of 2000, the stock market has experienced, and it may continue to experience, significant price and volume fluctuations. These fluctuations have particularly affected the market prices of equity securities of many small capitalization companies, like Matrixx, that are not yet profitable or that experience low or inconsistent earnings. Often, the effect on the price of such securities is disproportionate to the operating performance of such companies. In our case, such

broad market fluctuations may adversely affect our stockholders' ability to dispose of their shares of Matrixx at a price equal to or above the price at which they purchased such shares.

***

PART II

OTHER INFORMATION

Item 1. Legal Proceedings

The Company is subject to legal proceedings and claims that arise in the ordinary course of business. In the opinion of management, the amount of ultimate liability with respect to these actions will not materially affect the Company's financial position or results of operations.

Item 6. Exhibits and Reports on Form 8-K

A. Exhibits

Exhibit No.	Title
3.01	Articles of Incorporation and Amendments thereto of the registrant (1)
3.02	Bylaws of the registrant (1)
4.01	Rights Agreement dated as of July 22, 2002 by and between the registrant and Corporate Stock Transfer, Inc. (2)
10.01	Second Modification Agreement dated as of July 2, 2003 by and among Matrixx

	Initiatives, Inc., Zicam, LLC and Comerica Bank (3)
31.1*	Certification of CEO pursuant to Section 302 of Sarbanes-Oxley Act of 2002.
31.2*	Certification of CFO pursuant to Section 302 of Sarbanes-Oxley Act of 2002.
32.1*	Certification pursuant to 18 U.S.C. Section 1350.
32.2*	Certification pursuant to 18 U.S.C. Section 1350.

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* Filed with this Form 10-Q.

(1) Incorporated by reference to the Company's Amendment No. 1 to Form 8-A, filed June 18, 2002, file number 000-27646.

(2) Incorporated by reference to the Company's registration statement on Form 8-A, filed July 23, 2002, file number 000-27646.

(3) Incorporated by reference to the Company's quarterly report on Form 10-Q filed August 14, 2003, file number 000-27646.

B. Reports on Form 8-K

On July 24, 2003, the Company filed a report on Form 8-K regarding the reporting of the Company's earnings for the second quarter of fiscal 2003.

On August 14, 2003, the Company filed a report on Form 8-K regarding the introduction of a new and improved swab product, the settlement of the Company's legal proceedings against Zila, Inc. and IST and certain related adjustments to the

Company's second quarter earnings for fiscal 2003.

On September 30, 2003, the Company filed a report on Form 8-K regarding the provision of updated earnings guidance for fiscal 2003.

On October 23, 2003, the Company filed a report on Form 8-K regarding the reporting of the Company's earnings for the third quarter of fiscal 2003.

SIGNATURES

In accordance with the requirements of the Securities Exchange Act of 1934, the registrant has caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Matrixx Initiatives, Inc.

/s/ Carl J. Johnson

Carl J. Johnson
President and
Chief Executive Officer

/s/ William J. Hemelt

William J. Hemelt
Executive Vice
President,
Chief Financial Officer,
Treasurer and Secretary

November 11, 2003

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APPENDIX D.5

LONGO DECLARATION EX. 6

MATRIXX PRESS RELEASE, JAN. 7, 2004

[Graphic omitted]

Matrixx Initiatives, Inc. Revises Guidance Upward for 2003 Fiscal Year

1/7/2004 7:12:39 PM ET

PHOENIX, Jan 7, 2004 / PRNewswire-FirstCall via Comtex/ –

Matrixx Initiatives, Inc. (Nasdaq: MTXX), developer and distributor of the expanded line of Zicam® Cold Remedy products, today upwardly revised its guidance for fiscal year 2003. The Company expects total 2003 revenues to grow by greater than 80 percent compared to 2002 and fully diluted earnings per share to be in the range of $0.33 to $0.38. In 2002 Matrixx reported net sales of $23.5 million and earnings per share of $0.14 (exclusive of a one-time deferred tax asset accrual). This updates the Company's previous guidance of a 50% increase in revenue and earnings per share of $0.25-$0.30. The increase in the guidance for 2003 reflects a much greater incidence of colds than previously anticipated.

About Matrixx Initiatives, Inc.

Matrixx Initiatives, Inc. is engaged in the development, manufacture and marketing of over-the-counter (OTC)-pharmaceuticals which utilize innovative drug delivery systems. Zicam, LLC, its wholly-owned subsidiary, produces, markets and sells Zicam® Cold Remedy nasal gel, a patented,

homeopathic remedy that has been clinically proven to reduce the duration and severity of the common cold. In studies published in the October 2000 issue of ENT – Ear, Nose and Throat Journal, and separately in the January 2003 issue of QJM: An International Journal of Medicine, the Zicam Cold Remedy nasal gel product was shown to reduce the duration of the common cold. The Company also manufactures and markets a full line of Zicam brand pharmaceuticals, including Zicam Cold Remedy Swabs; Zicam Kids Size Cold Remedy Swabs; Zicam Cold Remedy Oral Mist, Zicam Cold Remedy Chewables, Zicam Cold Remedy RapidMelts, Zicam Allergy Relief, Zicam Extreme Congestion Relief; Zicam Sinus Relief; and Zicam Nasal Moisturizer. For more information regarding Matrixx products, go to www.zicam.com. To find out more about Matrixx Initiatives, Inc. (Nasdaq: MTXX), visit our website at www.matrixxinc.com. For additional information, contact William Hemelt, executive vice president and chief financial officer, 602-387-5353, whemelt@matrixxinc.com, or Lynn Romero, investor relations, at 602-387-5353, lromero@matrixxinc.com. Matrixx is located at 2375 East Camelback Road, Suite 500, Phoenix, Arizona 85016.

Matrixx Forward Looking Statement Disclaimer:

This news release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements regarding the Company's expectations that it will achieve in 2003 revenue growth of greater than 80% over 2002, and fully diluted earnings per share of $0.33 to $0.38 EPS for 2003. These forward-looking statements are based on the

Company's expectations and are subject to a number of risks and uncertainties, many of which cannot be predicted or quantified and are beyond the Company's control. Actual results could differ materially from those set forth in, contemplated by, or underlying the forward-looking statements. Some factors that could cause actual results to differ materially from the Company's expectations include issues that may arise in the process of finalizing the Company's financial statements for 2003. Other factors that could cause actual results to differ materially from the Company's expectations are described in the Company's most recent Quarterly Report on Form 10-Q filed pursuant to the Securities and Exchange Act of 1934 in the section entitled 'Management's Discussion and Analysis of Financial Condition and Results of Operations' under the subheading 'Risk Factors' filed pursuant to the Securities Exchange Act of 1934.

SOURCE Matrixx Initiatives, Inc.

William Hemelt, Chief Financial Officer, whemelt@matrixx.com or Lynn Romero, Investor Relations, lromero@matrixxinc.com, both of Matrixx Initiatives, Inc., +1-602-387-5353

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News Release Index

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APPENDIX D.6

LONGO DECLARATION EX. 7

DOW JONES NEWS SERVICE ARTICLE, JAN. 30, 2004

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Dow Jones News Service

January 30, 2004 Friday 10:01
PM GMT

LENGTH: 1008 words

HEADLINE: IN THE MONEY: FDA Looks Into Complaints About Zicam

BODY:

By Carol S. Remond
A Dow Jones Newswires Column

NEW YORK (Dow Jones)--The Food and Drug Administration is looking into complaints that an over-the-counter common-cold medicine manufactured by a unit of Matrixx Initiatives Inc. (MTXX) may be causing some users to lose their sense of smell.

The FDA's interest follows at least three lawsuits filed by individuals against Matrixx and Zicam LLC, a wholly-owned subsidiary, by users of Zicam Cold

Remedy, a nasal spray designed to deliver a zinc gel into the nasal opening.

A spokesman for Matrixx declined to comment on the lawsuits.

Matrixx has not disclosed the lawsuits or that the FDA is looking into complaints that users of Zicam Cold Remedy lost their sense of smell, a condition called anosmia. None of the lawsuits specify damages being sought.

A spokeswoman for the FDA said the agency "is aware of problems (that) people are reporting" and is investigating the complaints. The FDA spokeswoman would not say how many complaints were received. The spokeswoman said generally any investigation like this would involve contacting the complainants and the company manufacturing the product.

Matrixx Chief Financial Officer William Hemelt said that Zicam Cold Remedy, one of 10 Zicam products, accounted for about 60% of Matrixx' revenues last year. Hemelt declined to comment on the lawsuits and said that the company's policy is to disclose lawsuits that "are considered material to the company or outside ordinary course of business." Hemelt also declined to comment on the fact that the FDA is looking into complaints relating to one of the company's products. "Our policy is not to comment on any discussion or communication with any regulatory authorities," Hemelt said.

Matrixx' filings with the Securities and Exchange Commission show that Zicam products "are subject to regulation by the FDA, including regulations with respect to labeling of products, approval of ingredi-

ents in products, claims made regarding the products, and disclosure of product ingredients."

According to some studies, the intake of zinc, either orally or through the nasal passage, may help combat cold symptoms. However, other studies, conducted on animals, have found that high concentration of Zinc injected through the nose may cause anosmia.

In information provided to Dow Jones, Matrixx acknowledges that some studies have "attempted to link nasal products containing Zinc to the onset of anosmia." But the company argues that this research is based on products containing zinc sulfate, and not zinc gluconate, the solution contained in Zicam Cold Remedy. Matrixx argues that "zinc gluconate has properties that are significantly different from those of zinc sulfate."

Some medical experts seem to disagree with Matrixx' views, however.

Robert Henkin of the Taste and Smell Clinic in Washington, D.C., says that there is not much difference between the two zinc compounds. According to Henkin, when it comes to the injection of zinc through the nose, it's not about compound but rather about concentration.

"When delivered in a spray, it's possible to have a high enough concentration of zinc to injure the olfactory epithelium," Henkin said. Henkin cautioned that high concentration of zinc injected through the nose is only one of the many reasons why cold sufferers may lose their sense of smell. "It's clear that it could be related, but there could be other things as well, including the viral infection itself."

In a presentation to the American Rhinologic Society last September in Orlando, Dr. Bruce Jafek, Dr. Miriam Linschoten and Dr. Bruce Murrow from the Department of Otolaryngology at the University of Colorado School of Medicine, cautioned against the use of zinc spray. "Zinc ions remain toxic to human olfactory epithelium and continued reports of total, probably irreversible, anosmia, can be expected as long as intranasal zinc gluconate gel (Zicam) continues to be used," according to a summary of the presentation included in a program for the conference.

Jafek wasn't available for comment.

The first suit against Matrixx was filed last October in the U.S. District Court, Western District of Michigan. In that complaint, Dennis Christensen says that he felt an immediate and intense "stinging and/or burning sensation in his nose" after using Zicam Cold Remedy. "Since this one and only use of Zicam Cold Remedy Nasal Spray, plaintiff Dennis Christensen has totally lost his sense of smell," according to the complaint.

In its answer filed Jan. 9, Matrixx said it lacked sufficient information to answer the complaint. Matrixx said Zicam is a drug that has met all of the FDA's "requirements to lawfully market an over the counter homeopathic drug in interstate commerce in the U.S."

A second lawsuit was filed in the Circuit Court of Etowah County in Alabama on Dec. 18. That suit filed by Janie Sutherland also names Wal-Mart Stores Inc. (WMT) as a defendant.

In an answer filed on Jan. 22, Matrixx denied allegations made in the complaint. Wal-Mart also denied the charges.

A spokeswoman for Wal-Mart declined to comment about the lawsuit.

A third lawsuit was filed last week in the Superior Court of the State of Arizona in Maricopa County. In that suit, three plaintiffs allege that they lost their sense of smell and taste immediately after using Zicam Cold Remedy.

Matrixx' CFO Hemelt declined to comment on whether a recent drop in the price of the company's shares was related to the lawsuits.

Matrixx' stock reached a 52-week high of $20.89 a share on Jan. 8, a day after the company said it expected total revenues for its fiscal year 2003 to grow 80% compared to 2002. Matrixx said it expected fully diluted earnings per share to be between 33 cents and 38 cents.

Matrixx's stock closed at $13.55 a share Friday, down a penny.

(Carol S. Remond is one of four "In The Money" columnists who take a sophisticated look at the value of companies and their securities and explore unique trading strategies.)

-By Carol S. Remond; Dow Jones Newswires; 201 938 2074; carol.remond@dowjones.com

NOTES: 70768;
PUBLISHER: Dow Jones & Company

LOAD-DATE: December 15, 2004

APPENDIX D.7

LONGO DECLARATION EX. 8

MATRIXX PRESS RELEASE, FEB. 2, 2004

[Graphic omitted]

2/2/2004 1:29:59 PM ET

MATRIXX INITIATIVES REAFFIRMS SAFETY OF INTRANASAL ZICAM COLD REMEDY

Matrixx Initiatives, Inc., the manufacturer of Zicam® Cold Remedy, responds to the Dow Jones 'In The Money report: FDA Looks Into Complaints About Zicam,' by Carol S. Remond, alleging that the FDA is investigating consumer complaints regarding intranasal zinc gluconate-induced loss of smell.

Matrixx Initiatives, Inc., the manufacturer of Zicam® Cold Remedy, is not aware of an FDA inquiry into the safety of our intranasal zinc-gluconate products, as alleged by Carol S. Remond's column Dow Jones 'In The Money report: FDA Looks Into Complaints About Zicam.'

All Zicam products are manufactured and marketed according to FDA guidelines for homeopathic medicine. Our primary concern is the health and safety of our customers and the distribution of factual information about our products. Matrixx believes statements alleging that intranasal Zicam products cause anosmia (loss of smell) are completely unfounded and misleading.

In no clinical trial of intranasal zinc gluconate gel products has there been a single report of lost or diminished olfactory function (sense of smell). Rather, the safety and efficacy of zinc gluconate for the treatment of symptoms related to the common

cold have been well established in two double-blind, placebo-controlled, randomized clinical trials. In fact, in neither study were there any reports of anosmia related to the use of this compound. The overall incidence of adverse events associated with zinc gluconate was extremely low, with no statistically significant difference between the adverse event rates for the treated and placebo subsets.

A multitude of environmental and biologic influences are known to affect the sense of smell. Chief among them is the common cold. As a result, the population most likely to use cold remedy products is already at increased risk of developing anosmia. Other common causes of olfactory dysfunction include age, nasal and sinus infections, head trauma, anatomical obstructions, and environmental irritants.

The circumstances surrounding the development of Ms. Remond's column are extremely suspect. The article appeared online in public financial message boards almost immediately following its availability through the Dow Jones 'In The Money' subscription-only service. At least one of these message board postings was made by a registered username frequently used by Floyd Schneider, a defendant currently being sued for defamation by Matrixx Initiatives. From at least August 2001 to the present, Schneider has posted false and defamatory statements about Matrixx on various Internet message boards using a variety of anonymous aliases. It has come to our attention that Schneider has also attempted to interfere with Matrixx' business by contacting our retail customers.

Ms. Remond's article appears on today's Dow Jones Newswire the very day that Matrixx Initiatives is

deposing Schneider. We believe that the timing of this article was manipulated by Schneider to interrupt the deposition process. We know that Ms. Remond and Schneider were in close communication during the development of Ms. Remond's article and even discussed the disclosure statement detailing the basis for our suit against Schneider, which has not yet been made public. Therefore, it is particularly troubling that Ms. Remond neglected to mention the defamation action or that Schneider was one of her chief sources of information. We consider her failure to mention these facts to be a significant omission in fair and balanced reporting.

Matrixx Initiatives would like to underscore that we intend to vigorously pursue those individuals involved in any effort to improperly discredit the company and its products. Furthermore, we strongly urge Dow Jones to open its own investigation to determine whether Dow Jones' credibility was undermined by the use of copyrighted material in an attempt to do further harm to the value and reputation of Matrixx Initiatives and its products.

SOURCE: Matrixx Initiatives, Inc.

D.J. Storch & Associates Robert Murphy, 908-273-1400

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APPENDIX D.8

LONGO DECLARATION EX. 9

GOOD MORNING AMERICA TRANSCRIPT, FEB. 6, 2004

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[EOF999]

[STORY: COLD REMEDY CONCERNS]

[STORY2: FDA INVESTIGATES CLAIMS OF LOSS OF SENSE OF SMELL]

[CORR: JOHN FERRUGIA]

[CORLOC: DENVER, CO USA]

[1]08:07:37 CHARLES GIBSON (ABC NEWS)
All right. Thanks very much, Tony. And thanks to all those local stations who told you what's going on in your neighborhood.

[1]08:07:43 CHARLES GIBSON (ABC NEWS)
(OC) Well, "Good Morning America" has teamed up with our Denver affiliate, KMGH, for an investigation into a popular cold remedy. The FDA is looking into complaints from consumers who allege that this product caused them to lose their sense of smell. Here's KMGH reporter John Ferrugia.

[1]08:08:02 JOHN FERRUGIA (ABC NEWS)
(VO) Linda Bayley has lost her sense of smell.

[1]08:08:04 LINDA BAYLEY (LOST HER SENSE OF SMELL)
It's just not fair. It's not fair.

[1]08:08:08 JOHN FERRUGIA (ABC NEWS)
(VO) And according to doctors at the University of Colorado Center for Taste and Smell Disorders, it's not likely she will ever get it back.

[1]08:08:15 LINDA BAYLEY (LOST HER SENSE OF SMELL)
And it's just such a loss. All because I used a product.

[1]08:08:18 JOHN FERRUGIA (ABC NEWS)
(VO) She claims that product is Zicam Gel, which contains zinc luconate and is applied in the nose to reduce the duration of the common cold. Bayley is a colleague at KMGH, and after she brought her story to our attention, we learned consumers around the country are making the same complaint.

[1]08:08:34 DOCTOR BRUCE JAFIC (DIAGNOSED PATIENTS WITH LOSS OF SMELL)
Let's take a look in your nose.

[1]08:08:36 JOHN FERRUGIA (ABC NEWS)
(VO) Dr. Bruce Jafic has discovered more than a dozen patients with the same troubles as Linda, after using the Zicam product.

[1]08:08:43 LINDA BAYLEY (LOST HER SENSE OF SMELL)
There's no doubt in my mind that it's a cause and effect. Just because, I took it, it burned like crazy. The next day I didn't have a sense of smell.

[1]08:08:51 JOHN FERRUGIA (ABC NEWS)
(VO) It turns out the potential hazards of zinc compounds used nasally are well known. In the 1930's, a sink compound, used nasally as a polio vaccine,

resulted in as many as 10 percent of the patients losing their sense of smell.

[1]08:09:05 JOHN FERRUGIA (ABC NEWS) (OC) Permanently?

[1]08:09:05 DOCTOR BRUCE JAFIC (DIAGNOSED PATIENTS WITH LOSS OF SMELL) Permanently. It has been used in animal experiments, particularly in mice and rats, in which the purpose was to put the zinc into the nose to destroy the sense of smell.

[1]08:09:15 JOHN FERRUGIA (ABC NEWS) (VO) Matrix Initiatives, the manufacturer of Zicam, declined and on-camera interview. But tells us the zinc compound they use in their nasal gel is safe and different from the one used in the polio vaccine or on lab animals. In an e-mail, Matrix said the allegations are completely unfounded and misleading.

[GRAPHICS: QUOTES FROM MATRIX E-MAIL]

[1]08:09:32 JOHN FERRUGIA (ABC NEWS) (VO) It noted a multitude of environmental and biologic influences are known to affect the sense of smell. The company also said their product's safety has been well established in two double-blind, placebo-controlled, randomized clinical trials. But both University of Colorado experts examined the company's studies, and were not swayed. The doctors will soon publish a paper warning about the need to further study the potential dangers of zinc in nasal cold remedies. Meantime, Linda Bayley and others are left to ponder a future where some simple pleasures may be forever out of their reach.

[1]08:10:05 LINDA BAYLEY (LOST HER SENSE OF SMELL)
When people are closest to you, your family, it's not something you think about, but being able to smell them. My little baby cousin. You know, I can't smell babies anymore.

[1]08:10:16 CHARLES GIBSON (ABC NEWS)
(OC) And John Ferrugia is joining us now from Denver. John, I, I know this product comes in a number of forms.

[GRAPHICS: NASAL SPRAY DANGERS]

[1]08:10:22 CHARLES GIBSON (ABC NEWS)
(OC) I mean, it comes in a, in a tablet form, I think, and in an oral mist, as well. Is it just the nasal mist that people are worried about?

[1]08:10:29 JOHN FERRUGIA (ABC NEWS)
(OC) Yeah, Charlie. The FDA is looking at complaints only for this intranasal spray and the swabs that contain zinc gluconate.

[1]08:10:35 JOHN FERRUGIA (ABC NEWS)
(VO) And that zinc gluconate is listed right on the package.

[1]08:10:38 JOHN FERRUGIA (ABC NEWS)
(OC) This does not involve the lozenges or any Zicam products, and as you mentioned, there are several.

[1]08:10:43 CHARLES GIBSON (ABC NEWS)
(OC) Okay. And, and I, I got Matrix's response to the piece and to the, some of the complaints, but I know there've been lawsuits filed, as well. How have they responded to the lawsuits?

[1]08:10:53 JOHN FERRUGIA (ABC NEWS) (OC) Well, in fact there have been, so far, four lawsuits. Others are being prepared, anywhere from California to Michigan. And so far, Matrix -Initiatives has denied that there's any problem, saying that there is no liability. They're saying there's a lot of different reasons you can lose your sense of smell and Zicam isn't one of them.

[1]08:11:11 CHARLES GIBSON (ABC NEWS) (OC) All right, thanks. John Ferrugia reporting from our station KMGH in Denver.

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APPENDIX D.9

LONGO DECLARATION EX. 10

MATRIXX PRESS RELEASE, FEB. 6, 2004

[Graphic omitted]

2/6/2004 6:56 PM ET

UPDATE: MATRIXX INITIATIVES REAFFIRMS SAFETY OF INTRANASAL ZICAM(R) COLD REMEDY

PHOENIX, Feb 6, 2004 /PRNewswire-FirstCall via COMTEX/ --

Matrixx Initiatives, Inc., (Nasdaq: MTXX) the manufacturer of Zicam(R) Cold Remedy zinc products, said today that reports alleging anosmia—or loss of smell—in a small number of patients using zinc gluconate intranasal gels for the treatment of the common cold are completely unfounded and misleading. At this time, the company is not aware of any investigation by a regulatory body with regard to the product.

We want to assure our consumers that Zicam Cold Remedy intranasal zinc gluconate products are manufactured and marketed according to Food and Drug Administration guidelines for homeopathic medicine. Our primary concerns are the health and safety of those who use Zicam Cold Remedy nasal gels and the distribution of factual information about our products.

In no clinical trial of intranasal zinc gluconate gel products has there been a single report of lost or diminished olfactory function (sense of smell). Rather, the safety and efficacy of zinc gluconate for the treatment of symptoms related to the common

cold have been well established in two double-blind, placebo-controlled, randomized clinical trials. In fact, in neither study were there any reports of anosmia related to the use of this compound. The overall incidence of adverse events associated with zinc gluconate was extremely low, with no statistically significant difference between the adverse event rates for the treated and placebo subsets.

A multitude of environmental and biologic influences are known to affect the sense of smell. Chief among them is the common cold. As a result, the population most likely to use cold remedy products is already at increased risk of developing anosmia. Other common causes of olfactory dysfunction include age, nasal and sinus infections, head trauma, anatomical obstructions, and environmental irritants.

Zinc and Loss of Smell Research

A few researchers have attempted to link nasal products containing zinc to the onset of anosmia. However, this hypothesis is based on data from polio studies conducted in the 1930s using a concentrated *zinc sulfate* solution. Current nasal products, such as Zicam Cold Remedy, contain *zinc gluconate*, which is an entirely different compound.

Zinc sulfate is a mineral salt that reacts with water to produce a strong acid (sulfuric acid) and zinc oxide, which is practically insoluble in water. By comparison, zinc gluconate is a weak organic salt that dissolves to form positively charged zinc ions and negatively charged gluconate—a naturally occurring, non-toxic compound found in all human tissues. Zicam Cold Remedy is a buffered gel,

formulated to have a neutral pH—i.e., a pH that approximates that of the nasal cavity.

About Matrixx Initiatives, Inc.

Matrixx Initiatives, Inc. is engaged in the development, manufacture and marketing of over-the-counter (OTC) pharmaceuticals which utilize innovative drug delivery systems. Zicam, LLC, its wholly-owned subsidiary, produces, markets and sells Zicam® Cold Remedy nasal gel, a patented, homeopathic remedy that has been clinically proven to reduce the duration and severity of the common cold. In studies published in the October 2000 issue of ENT — Ear, Nose and Throat Journal, and separately in the January 2003 issue of QJM: An International Journal of Medicine, the Zicam Cold Remedy nasal gel product was shown to reduce the duration of the common cold. The Company also manufactures and markets a full line of Zicam brand pharmaceuticals, including Zicam Cold Remedy Swabs; Zicam Kids Size Cold Remedy Swabs; Zicam Cold Remedy Oral Mist, Zicam Cold Remedy Chewables, Zicam Cold Remedy RapidMelts, Zicam Allergy Relief, Zicam Extreme Congestion Relief; Zicam Sinus Relief; and Zicam Nasal Moisturizer. For more information regarding Matrixx products, go to www.zicam.com. To find out more about Matrixx Initiatives, Inc. (Nasdaq: MTXX), visit our website at www.matrixxinc.com. For additional information, contact William Hemelt, executive vice president and chief financial officer, 602-387-5353, whemelt@matrixxinc.com, or Lynn Romero, investor relations, at 602-387-5353, lromero@matrixxinc.com. Matrixx is located at 2375 East Camelback Road, Suite 500, Phoenix, Arizona 85016.

SOURCE Matrixx Initiatives, Inc.

William Hemelt, executive vice president and chief financial officer, whemelt@matrixxinc.com, or Lynee Romero investor relations, lromero@matrixxinc.com, both of Matrixx Initiatives, Inc., +1-602-387-5353

http://www.matrixxinc.com

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News Release Index

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APPENDIX D.10

LONGO DECLARATION EX. 11

MATRIXX 8-K, FEB. 27, 2004

[Graphic and cover material omitted]

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934

February 19, 2004 (Date of earliest event reported)

MATRIXX INITIATIVES, INC.

(Exact Name of Registrant as Specified in its Charter)

DELAWARE	0-27646	87-0482806
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

4742 North 24th Street, Suite 455
Phoenix, Arizona 85016
(Address of Principal Executive Offices) (Zip Code)

Registrant's telephone number, including area code
(602) 387-5353

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ITEM 5. OTHER EVENTS

Matrixx Initiatives, Inc., the manufacturer of Zicam® Cold Remedy zinc products, convened a two-day meeting of a panel of physicians and scientists to review current information on smell disorders. The meeting was held in response to a poster presentation at the American Rhinological Society in September 2003 alleging an association between the use of Zicam and the onset of smell disorders.

The incidence of smell disorders in the United States is reported at 1-2% of the population. Reported post-marketing subjective complaints of distortion of sense of smell associated with Zicam are well below national levels.

In the opinion of the panel, there is insufficient scientific evidence at this time to determine if zinc gluconate, when used as recommended, affects a person's ability to smell.

Panel members noted that upper respiratory infection is the most common cause of disorders of smell; and, therefore, any product to treat upper respiratory symptoms may be mistakenly associated with distortion of sense of smell.

The panel recommended additional animal and human studies to further characterize these post-marketing complaints. Study findings are expected to be available in 12 months.

Panel members included Lawrence DeSanto, M.D., Mayo Clinic, Scottsdale; Joseph E. Dohar, M.D., Children's Hosital of Pittsburgh; Aiden L. Doyle, M.D., FACS, Pharmacetical Consultant, Central Nervous System; Jack M. Gwaltney Jr., M.D., University of Virginia Health System; Kathleen M. Guthrie, Ph.D., Department of Biomedical Science, Florida Atlantic University; Judith K. Jones, M.D., Ph.D., Pharmacoepidemiologist; Bao-Anh Nguyen-Khoa, Pharm. D., M.P.H., Pharmacoepidemiologist; Burton M. Slotnick, Ph.D., Department of Psychology, University of South Florida; Michael Zmuda, Ph.D., Regulatory Consultant.

SIGNATURES

Pursuant to the requirements of the Securities and Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

MATRIXX INITIATIVES, INC.
(Registrant)

/s/ William J. Hemelt
William J. Hemelt
Executive Vice President, Chief Financial Officer, Treasurer and Secretary

Date: February 27, 2004

APPENDIX D.11

LONGO DECLARATION EX. 12

MATRIXX 2003 10-K, MAR. 19, 2004

[Graphic and cover material omitted]

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549-1004

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2003

OR

For the transaction period from _____ to _____

Commission File No. 0-27646

MATRIXX INITIATIVES, INC.

(Name of business issuer in its charter)

Delaware	**87-0482806**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)

4742 N. 24th Street
Suite 455

Phoenix, AZ 85016
602-385-8888
(Address of principal executive offices, Issuer's Telephone Number, Including Area Code)

Securities registered pursuant to Section 12(b) of the Act: None

Securities registered pursuant to Section 12(g) of the Act:

Title of Each Class	Name of Each Exchange on Which Registered
Common Stock, $.001 par value	Nasdaq National Market

Indicate by check mark whether the Registrant (1) filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES ☒ NO ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K, is not to be contained herein, and will not be contained, to the best of the Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

Indicate by check mark whether the registrant is an accelerated filer (as defined in Exchange Act Rule 12b-2). YES ☐ NO ☒

As of March 1, 2004, 9,479,601 shares of the Registrant's Common Stock were outstanding. As of March 1, 2004, the market value of the Registrant's Common Stock (based on the closing price of the shares on the Nasdaq National Market), excluding shares held by affiliates, was approximately $95 million.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's definitive proxy statement prepared in connection with the Registrant's 2004 annual meeting of stockholders are incorporated by reference into Part III, Items 10, 11, 12, 13 and 14 of this Form 10-K.

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Unless otherwise indicated in this Form 10-K, "Matrixx," "us," "we," "our", "the Company" and similar terms refer to Matrixx Initiatives, Inc. and its subsidiaries. "Zicam" is a registered trademark of our subsidiary, Zicam, LLC, and the Matrixx name and logo are trademarks of the Company.

PART I

ITEM 1. BUSINESS

Introduction

We develop, produce, market and sell innovative, over-the-counter (OTC) pharmaceutical products with an emphasis on those which utilize unique or novel delivery systems. Through our subsidiary, Zicam, LLC, we produce, market and sell 10 different products under the Zicam® brand: Zicam Cold Remedy nasal gel, a patented, homeopathic remedy that has been clinically proven to reduce the duration and severity of the common cold; two related nasal swab cold remedy products – Zicam Cold Remedy Swabs and Zicam Cold Remedy Swabs – Kids Size; three homeopathic oral delivery cold remedy products – Zicam Cold Remedy Chewables, Zicam Cold Remedy RapidMelts and Zicam Cold Remedy Oral Mist; Zicam Allergy Relief, a homeopathic nasal gel formula designed to control allergy symptoms for sufferers of hay fever and other upper respiratory allergies; Zicam Extreme Congestion Relief, a nasal gel formula designed to provide fast-acting, long-lasting relief of nasal congestion; Zicam Sinus Relief, a nasal gel formula that enhances the benefits of Extreme Congestion Relief with menthol and eucalyptus for improved feeling of sinus pressure relief; and Zicam Nasal

Moisturizer, a non-medicated nasal moisturizer.

We were incorporated in Utah in 1991. Prior to July 2001, as Gum Tech International, Inc., our principal business was the development, manufacture and sale of nutritional and healthcare-related chewing gum products. In 1999, we formed Gel Tech, L.L.C., in which we owned 60%. The business of Gel Tech was to develop and produce homeopathic nasal gel products based on a proprietary zincum gluconicum delivery system. In July 2001, we exited the chewing gum business with the sale of substantially all of our chewing gum assets and business to the Wm. Wrigley Jr. Company ("Wrigley"). In December 2001, we acquired the remaining 40% of Gel Tech and changed its name to Zicam, LLC. On June 18, 2002, we reincorporated in Delaware and changed our name from Gum Tech International, Inc. to Matrixx Initiatives, Inc.

Our principal executive offices were relocated in February 2004 to 4742 N. 24th Street, Suite 455, Phoenix, AZ 85016 and our telephone number has changed to (602) 385-8888.

Markets and Company Products

All 10 of our Zicam products are targeted at the cough and cold market category. That market, which is estimated at more than $3 billion annually in retail sales in the United States, includes a wide variety of tablets, liquids, nasal sprays and syrups that remedy and/or provide relief to cold, allergy and sinus congestion sufferers. The largest sub-segment of the cough and cold category includes products formulated to relieve symptoms associated with the common cold. It is estimated that more than one

billion common colds occur in the United States each year, with over 100 million of these colds resulting in lost days of school or work, or some level of restricted activity. Colds are estimated to occur at a rate of two to five per person (six to eight per child) each year. The market for allergy relief products covers a much smaller segment of the population, estimated at 35 million people in the United States. However, allergy sufferers, compared to cold sufferers, are more likely to require medication for a much longer period of time to relieve allergy symptoms.

Our biggest selling product, Zicam Cold Remedy, which accounted for approximately 40% of net sales during 2003 is a homeopathic nasal gel product based on our patented zincum gluconicum delivery system. The original product in a nasal pump bottle was introduced in 1999. Sales of Zicam Cold Remedy have grown steadily since its introduction as customer awareness of the product has increased as a result of our marketing and public relations efforts, and word-of-mouth experience by consumers. Zicam Cold Remedy was formulated to reduce the duration and severity of the common cold. In a study published in the October 2000 issue of the ENT- Ear, Nose & Throat Journal, Zicam Cold Remedy was shown to reduce the duration of the common cold when taken at the onset of symptoms. In a separate study published in the January 2003 issue of QJM: An International Journal of Medicine, zincum gluconicum nasal gel (Zicam Cold Remedy) was shown to reduce the duration and symptoms of the common cold when treatment was started as late as the second day of illness. We believe Zicam Cold Remedy is unique in the cough and cold market category due to the claims that we are able to make

regarding the product's ability to reduce the duration of the common cold. To our knowledge, only two other products in the cough and cold category (including competing generic copies of that product) are able to make a similar claim.

Zicam Cold Remedy Swabs and Zicam Cold Remedy Swabs - Kids Size contain the same ingredients as Zicam Cold Remedy and were introduced in late 2002 to appeal to consumers who dislike nasal sprays. Both of these swab products have been well received by the retail trade, though we have been limited in meeting consumer demand, particularly for the adult swab product, due to production constraints of our supplier. We experienced a backlog in orders in late December 2002 and again in December 2003. As a result of the manufacturer's inability to meet our swab production requirements in 2002 and higher costs imposed unilaterally by the manufacturer, we developed a new swab product in 2003 that is produced by a different manufacturer. We began shipping the new swab product to retailers in February 2004. We will continue to receive shipments of the old product design until the expiration of the manufacturing contract on March 31, 2004. Because of the time required for start-up, deliveries of the new swab did not alleviate the most recent backlog until early March 2004. The kid's size swab product has not been in a back-order situation. We expect that the manufacturer of the new swab design will be able to meet our future requirements in the next cold season, but we intend to build inventory of swab products prior to the next cold season to further ensure our ability to meet future demand for the swab products. The two swab

products accounted for approximately 25% of net sales for 2003.

We introduced three oral delivery forms of Zicam Cold Remedy products in late 2003 – Zicam Cold Remedy Chewables, Zicam Cold Remedy RapidMelts, and Zicam Cold Remedy Oral Mist. These products were designed to meet the needs of customers who dislike nasal applications. All three rapidly deliver a dose of ionic zinc to the oral mucosa in contrast with zinc lozenges which require approximately 15-20 minutes to dissolve. We believe that this feature allows the consumer to avoid much or all of the stomach upset that has been associated with the zinc lozenges on the market. We expect future distribution of these three products will increase significantly, as initially most major national retailers sold only one or two of these new products. These three products accounted for almost 15% of our net sales in 2003.

Zicam Allergy Relief, also a homeopathic nasal gel formula, was introduced in 2000. Zicam Allergy Relief is designed to control allergy symptoms for sufferers of hay fever and other upper respiratory allergies. An initial double-blind scientific study indicated that Zicam Allergy Relief reduced the severity of symptoms resulting from these types of allergies. We believe Zicam Allergy Relief is distinctive from most allergy products available on the market due to the absence of side effects such as drowsiness or jitters. Zicam Allergy Relief accounted for almost 10% of net sales for 2003.

Three other Zicam nasal gel products were introduced in late 2002 – Extreme Congestion Relief, Sinus Relief and Nasal Moisturizer. Zicam Extreme

Congestion Relief is a nasal gel that combines the active ingredient oxymetazoline hydrochloride into our gel matrix and soothing aloe vera to provide fast-acting, long-lasting relief of nasal congestion and sinus pressure. Zicam Sinus Relief provides all of the benefits of the Extreme product with the aromatic strength of a cooling menthol/eucalyptus blend. Zicam Nasal Moisturizer is a non-medicated moisturizer that suspends aloe and eight other moisturizers in the gel matrix to help ensure constant, soothing relief for irritated nasal membranes. While greater retail distribution opportunities exist, these three products contributed approximately 10% of total 2003 net sales. We believe continued growth in sales from these three products is dependent on achieving much wider distribution among retailers, and in particular, among large nation-wide food, drug and mass marketers.

Business Strategy

Our objective is to become a recognized leader in providing OTC pharmaceutical products which utilize unique or novel delivery systems. To achieve our objective, the key elements of our business strategy include the following:

Expanding Marketing Efforts for Existing Products: We intend to continue to develop and refine our sales and marketing efforts to increase market penetration of our Zicam products in U.S. households. Such efforts include improving the timing and consistency of marketing activities compared to previous years, executing effective trial generating programs, implementing programs with retailers to enhance consumer awareness of our

products and seeking to increase recommendations from healthcare professionals. We are also implementing new, creative advertising approaches and public relations efforts. We believe these efforts will continue to build brand awareness, trial and sales of our products.

Capitalizing on Our Nasal Gel Technology and Know-How: We intend to leverage our nasal gel technology and know-how to develop additional gel delivery system product offerings that complement the current Zicam products. Additional gel technology products may include over-the-counter pharmaceutical ingredients that can be effectively delivered through our nasal gel delivery system. We believe extending the Zicam product line in this way will bring additional consumer awareness and expand our product presence and support from retailers.

Pursuing Additional Delivery Systems: Our success in expanding consumer acceptance of our nasal gel delivery system and growing the Zicam franchise confirms our belief that opportunities exist to pursue development of other unique and proprietary consumer healthcare product delivery systems. We are seeking to identify, through internal research and development efforts and through consideration of external opportunities, other growth opportunities for Matrixx and are specifically targeting product concepts in the analgesic and oral care markets as well as the cough and cold market category in which we currently operate.

Extending Sales Into New Markets: We continue to explore expanding sales into appropriate

international markets where sales prospects are favorable. Because of the complex and multiple regulatory environments, languages, customs, logistics and working capital requirements involved in developing these markets, we are exploring possible relationships with multi-national business organizations and established international distributors capable of introducing products and competing in international markets. However, we do not expect any revenue or net income impact in the near future.

Customers

We sell our products directly to major food, drug, mass market (e.g. Wal-Mart, Target) and wholesale warehouse retailers throughout the United States, and to distributors that sell to smaller retail establishments. Zicam Cold Remedy nasal pump, Zicam Cold Remedy Swabs – Adult Size and Zicam Allergy Relief are sold in virtually every major retail outlet in the country. Our seven other Zicam products have not achieved the same level of distribution, though two national retailers currently carry all 10 Zicam products. We are highly dependent on a small group of large national retailers for our product distribution, such that our top fifteen customers accounted for more than 80% of our net sales in 2003, and two customers, Wal-Mart and Walgreens, each accounted for more than 10% of our net sales in 2003. Our agreements with our customers generally provide for their ability to return unsaleable merchandise, including damaged product or out-of-date product. We provide in our financial results, as an offset against sales, an estimate for expected returns. Due to the continuing growth and success of the Zicam products, we have

not experienced unusual or excessive amounts of product returns, other than that which occurred in connection with excess production of Zicam Cold Remedy in late 1999 and early 2000 in connection with the original introduction of the product, which resulted in out-of-date products two years later. To the extent that any of our largest customers were to stop carrying our products for any reason, or were to fail to pay us for our products, our sales and financial results would be negatively impacted.

***

FDA and Other Government Regulation

We are subject to various federal, state and local laws and regulations affecting our business. All of our products are subject to regulation by the FDA, including regulations with respect to the approval of manufacturing processes and procedures, ingredients in the products, labeling and claims made. All of our Zicam Cold Remedy products, the three new oral delivery products, and Zicam Allergy Relief, are further subject to the requirements of the Homeopathic Pharmacopeia of the United States. Zicam Extreme Congestion Relief and Zicam Sinus Relief are subject to the requirements of the FDA as allopathic drugs. All of our claims and advertising are subject to the rules of the Federal Trade Commission (FTC). Although we believe that our products and claims comply in all material respects with the regulatory requirements, if the FDA or FTC were to determine that we are in violation of any such requirement, either agency could restrict our ability to market the products, change the claims that we make or cause us to remove the products from the market. It has been reported in the press

that the FDA is looking into customer complaints about our Cold Remedy nasal products, although we have not been advised by the FDA of such an inquiry.

***

Employees

As of December 31, 2003 we employed 15 people in our Phoenix, Arizona headquarters office. The 15 employees consist of six executive officers and individuals responsible for administrative, operations, marketing, sales, research and development, regulatory compliance, investor relations and accounting.

***

Competition

All of the Zicam products compete in the highly competitive cough and cold and allergy markets with a vast number of well-established brands marketed by large pharmaceutical and consumer products companies. Participants in the cough and cold and allergy markets compete primarily on the basis of price, quality of product and consumer awareness. Most of our competitors have substantially greater financial, marketing and other resources, longer operating histories, larger product portfolios and greater brand recognition than we do. With our limited resources, we are aiming to succeed in this category by emphasizing the unique claims regarding our products. Specifically, regarding Zicam Cold Remedy, our flagship product, we emphasize its ability to reduce the duration and severity of the common cold. Only two other products in the category (including competing generic copies)

are able to make a similar claim.

***

ITEM 3. LEGAL PROCEEDINGS

The Company is subject, from time to time, to legal proceedings and claims regarding adverse reactions to its products. From December 2003 through early March 2004, we were sued by over seventy individuals in six different lawsuits (including one lawsuit which has not yet been served on the Company) generally alleging that our Zicam Cold Remedy nasal pump product caused damage to the sense of smell and/or taste. The cases are Christensen et al. vs. Matrixx Initiatives, Inc. et al., filed October 13, 2003 in the United States District Court, Western District of Michigan, Southern Division, Case No. 4:03DV0146; Sutherland vs. Matrixx Initiative, Inc. et al., filed December 18, 2003 in the Circuit Court of Etowah, Alabama, Case No. CV-2003-1635-WHR (moved to United States District Court for the Northern District of Alabama, Middle Division); Nelson vs. Matrixx Initiatives, Inc. et al., filed December 8, 2003 in the Los Angeles Superior Court, Case No. YC048136; Bentley et al. vs. Matrixx Initiatives, Inc. et al., filed January 23, 2004 in the Superior Court of Arizona (Maricopa County), Case No. CV2004-001338; Ringbauer et al. vs. Matrixx Initiatives, Inc. et al., filed February 11, 2004 in the Superior Court of Arizona (Maricopa County), Case No. CV2004-002822 (moved to United States District Court for the District of Arizona, Case No. 04-CV-513); and Abramsen et al. vs. Matrixx Initiatives, Inc. et al., filed March 8, 2004 in the Superior Court of Arizona (Maricopa County), Case No. CV2004-04415. An investigative news

report by a national network program that was subsequently featured by several local stations across the country, which suggested the possibility of Zicam Cold Remedy negatively impacting a person's sense of smell and/or taste seemed to be related to the filing of the lawsuits. Also, to our knowledge, at least two plaintiffs' law firms are actively soliciting potential claimants through the internet and other media. As a result, additional lawsuits may be filed against the Company. It is very early in the discovery phase of the six lawsuits so it is unlikely than any of the cases will proceed to trial before the first quarter of 2005. It appears that each of the lawsuits, as well as the news media reports, is based on research and allegations regarding a connection between zinc sulfate and loss of sense of smell. Zicam Cold Remedy contains zinc gluconate, not zinc sulfate, which has very different properties than zinc sulfate. We believe the allegations relating to Zicam Cold Remedy are inappropriate and misleading. Zicam Cold Remedy has been studied in two independent, placebo-control studies. In those studies, there was no statistically significant difference in adverse events between the placebo and non-placebo group, and there were no indications in either group of an impairment to sense of smell. Further, the incidence of smell disorders is reported at 1-2% of the population on average, and is very common in those over age 50. Upper respiratory infections are among the most common cause of impairment to sense of smell. Therefore, any product such as Zicam Cold Remedy designed to treat upper respiratory illnesses may be mistakenly associated with distortion of sense of smell. The rate of reported complaints of distortion of sense of smell associated with Zicam Cold Remedy is well below these

national incidence levels. We have submitted all six lawsuits to our insurance carrier. We cannot predict the outcome of the litigation, but we will defend ourselves vigorously. If any liability were to result from one or more of these or future lawsuits, we believe our financial results could be materially impacted to the extent that such liability is not covered by insurance, as well as by the adverse publicity that may result.

***

PART II

ITEM 5. MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

Our common stock has been quoted for trading on the Nasdaq National Market since April 24, 1996. From then until June 19, 2002, our stock traded under the symbol "GUMM". Effective on June 20, 2002, in connection with our name change to Matrixx Initiatives, Inc., our stock trading symbol changed to "MTXX". The following table sets forth, for the quarters indicated, the range of high and low closing prices of our common stock as reported by the Nasdaq National Market.

	Market Price	
	High	Low
Fiscal Year 2002		
First Quarter	$ 8.64	$ 6.52
Second Quarter	$10.55	$ 8.00
Third Quarter	$10.66	$ 9.50
Fourth Quarter	$10.00	$ 7.80
Fiscal Year 2003		

First Quarter	$ 8.75	$ 6.56
Second Quarter	$ 8.65	$ 6.61
Third Quarter	$11.39	$ 6.75
Fourth Quarter	$18.28	$ 10.99
Fiscal Year 2004		
First Quarter (through March 1, 2004)	$19.45	$ 8.60

As of March 1, 2004, we had approximately 7,300 record and beneficial stockholders.

***

ITEM 6. SELECTED FINANCIAL DATA

The following table sets forth selected historical financial data for Matrixx for each of the years in the five-year period ended December 31, 2003, and where appropriate reflects results on a continuing and discontinued operations basis. The financial data presented below is derived from Matrixx's financial statements audited by independent auditors. We report Matrixx's and Zicam, LLC's financial results on a consolidated basis. On July 20, 2001, we sold substantially all of our chewing gum assets and business to Wrigley. Our financial results following this date reflect our former chewing gum operations as discontinued operations. On December 5, 2001, we acquired the remaining 40% interest in Gel Tech, L.L.C., making it a wholly-owned subsidiary of Matrixx. (In July 2002, the name of Gel Tech, L.L.C. was changed to Zicam, LLC). For additional information, see the financial statements of Matrixx and the notes thereto included elsewhere in this report. The following table should be read in conjunction with Item 7,

"Management's Discussion and Analysis of Financial Condition and Results of Operations" and is qualified by reference thereto and to Matrixx's financial statements and notes thereto.

(000's, except per share data)	2003	2002	2001	2000	1999
Net sales	$43,496	$23,548	$16,072	$10,817	$ 9,593
Net income (loss)					
— Continuing Operations	$ 3,344	$ 4,757*	$(4,799)	$(6,166)	$ (172)
— Discontinued Operations	$ —	$ —	$17,412	$(1,971)	$ (601)
Net income (loss) per share of common stock - -basic					
— Continuing Operations	$ 36	$ 50*	$(0 52)	$(0.69)	$ (0 06)
— Discontinued Operations	$ —	$ —	$ 1 88	$ (0 22)	$ (0 08)
Net income (loss) per share of common stock - diluted					
— Continuing Operations	$ .35	$ 50*	$ (0.52)	$ (0 69)	$ (0 06)
— Discontinued Operations	$ —	$ —	$ 1.88	$ (0.22)	$ (0 08)
Dividends per share	$ 0	$ 0	$ 0	$ 0	$ 0
Shares outstanding at year end	9,475	9,441	9,432	9,047	8,321
Total assets	$50,077	$47,185	$42,507	$16,981	$20,028
Long term obligations	$0	$0	$5,254	$0	$2,241
Stockholders' equity	$38,790	$35,155	$24,369	$10,448	$12,702

* Earnings for 2002 include the one-time recording of a deferred tax asset of approximately $3.4 million. Earnings per share for 2002 exclusive of this one-time accrual were $.14 per share.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Overview

In Fiscal 2001 we undertook a significant change in our strategic plan and related business operations by exiting the chewing gum business and refocusing entirely on the development, production and sale of over-the-counter pharmaceutical products. In July 2001, we sold substantially all of our assets and business related to our chewing gum operations to Wrigley. In December 2001, we acquired the remaining 40% interest of Gel Tech, making it a wholly-owned subsidiary of Matrixx. In July 2002, the name Gel Tech, L.L.C. was changed to Zicam, LLC. Our financial results reflect our former chewing gum operations as discontinued operations, and consequently these operations are not reflected in the following discussion and analysis. We report Zicam, LLC's financial results on a consolidated basis. We owned 60% of Zicam prior to December 5, 2001 and 100% on and subsequent to that date.

Our restructuring process continued in 2002 as we reincorporated in Delaware, changed our name to Matrixx Initiatives, Inc. and consolidated our operations in our Phoenix office. Moreover, as part of our focus on over-the-counter pharmaceutical products, we introduced five new Zicam nasal gel products in 2002, improved package graphics for the entire Zicam product line and engaged a new sales team to represent our products to retailers. We continued to expand the Zicam product line in 2003 by introducing three Zicam Cold Remedy oral products – Chewables, RapidMelts and Oral Mist.

Executive Summary

Net sales for 2003 increased to approximately $43.5 million, or 85% above net sales in 2002. Approximately one-half of the increase was attributable to increased sales of Zicam Cold Remedy nasal gel products and approximately 35% of the increase was attributable to the three new Zicam Cold Remedy oral products introduced in September 2003. Net sales in 2003 were impacted by a severe cold season that peaked in December 2003. However, we expect this trend of increasing net sales to continue as we improve consumer awareness of our products, increase distribution of our products, and introduce new products.

Net income for 2003 was approximately $3.3 million. Net income in 2002 was $4.8 million including a one-time tax benefit of approximately $3.4 million. Net income in future periods will be significantly affected by the level of sales, and the timing and amount of our advertising and research and development expenses. Expenditures for advertising and research and development will vary by quarter throughout the year and could be significantly different in 2004 than the amounts incurred in the same periods in earlier years. We expect that advertising expenses will be highest in the fourth and first quarters in conjunction with the cough and cold season.

The Company's management reviews several key performance indicators. First, we compare our annual sales and net income performance against our stated goal of 30% annual growth for each. For 2003, we exceeded both goals (ignoring the one-time tax benefit in 2002). We also monitor our share of

the cough and cold market. For the twelve months ended December 28, 2003, sales of our products achieved a share of about 1.3% of the entire cough and cold market compared to a share of 0.8% a year ago. We also measure our ability to maintain strong gross margins on our products. During 2003, our products averaged a gross margin of 69%, which was slightly below our target minimum of 70% due to the higher cost of the old swab product. In 2002, our gross margin averaged 71%. In addition, we evaluate our operating performance by reviewing, over time, our ability to decrease administrative and general costs as a percentage of net sales. In 2003, our administrative and general costs were 50% of our net sales compared to 66% for 2002. Finally, we review the distribution of our products by key national retailers. In 2003, our 15 largest customers carried, on average, six of our 10 Zicam products compared to three of our seven products in 2002. We expect to expand the distribution of our existing products among these retailers during the next year.

Critical Accounting Policies and Estimates

Our consolidated financial statements and accompanying notes have been prepared in accordance with generally accepted accounting principles applied on a consistent basis. The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting periods.

We regularly evaluate the accounting policies and estimates that we use to prepare our consolidated financial statements. In general, management's estimates are based on historical experience, on information from third party professionals and on various other assumptions that are believed to be reasonable under the facts and circumstances. Actual results could differ from those estimates made by management.

We believe that our critical accounting policies and estimates include the accounting for intangible assets and goodwill, accounting for income taxes, accounting for returns and allowances associated with our products and accounting for legal contingencies.

Intangible assets and goodwill: We recorded approximately $15.0 million in goodwill in connection with the 40% Zicam, LLC interest that we acquired from Zensano, Inc. in December 2001. Under SFAS 142, goodwill must be tested annually to identify a potential impairment and the amount of any impairment loss. Factors that could affect this analysis would be significant loss of market share, a general decline in Zicam product sales, higher than expected increases in expenses and various other matters. Any change in key assumptions about the business or prospects of Zicam, LLC, or any change in market conditions or other externalities affecting Zicam, LLC, could result in an impairment charge, and such a charge could have a material adverse effect on our financial condition and results of operations. The goodwill was recently evaluated in the third quarter of 2003 by an independent valuation firm and no impairment was found.

Accounting for income taxes: Due to our significant operating losses prior to 2001, we possess a sizeable tax loss carry-forward which can be used to reduce our taxable income in future periods. Due to our history of operating losses, we recorded a deferred tax valuation allowance in 2001 and prior years to offset the entire deferred tax asset arising from our tax loss carry-forward. However, due to the significant improvement in our net income in 2002, together with our expectation of continuing profitability in future years, we determined that we are more likely than not to realize the tax benefit associated with our tax loss carry-forward. Consequently, we reduced the deferred tax valuation allowance and recorded a large portion of the deferred tax asset in 2002. The effect of this change was a decrease in our income tax expense of approximately $3.4 million in 2002. In 2003, we recorded income tax expense based on our estimated effective income tax rate for the year and will continue to do so in future periods. In addition, we will continue to evaluate the deferred tax valuation allowance regularly and adjust the amount to reflect our expectation of our ability to realize the tax benefit arising from our tax loss carry-forward on a quarterly basis. Should there be a significant change in our expectations of future income, the impact of adjusting the deferred tax valuation allowance could be significant which would negatively impact our earnings.

Accounting for customer returns and allowances: We recognize revenues on the sale of our products when they are shipped from our warehouse facility, and at that time record a provision for estimated product returns. The estimate for product returns is

based on our historical experience of sales to retailers and is reviewed regularly to ensure that it reflects the liability associated with product returns. To date, our sales returns experience has been consistent with our estimate for returns, except for returns of outdated products arising from excess production during the introduction of Zicam Cold Remedy in the 1999-2000 cold season, which resulted in out-of-date product two years later. Currently, we are recording a provision of 3% of gross sales for the seven Zicam products introduced in 2002 or earlier for potential returns and allowances. In establishing the appropriate reserve level for the three new Zicam products introduced in the third quarter of 2003, we reviewed the similarities and differences of the three products relative to the seven Zicam products for which we now have several years of product return experience. Based on that review, we are recording a 7% provision of gross sales for these products. We will review the return provision regularly and adjust these reserve amounts as actual product return experience continues to develop. Should the actual level of product returns vary significantly from our estimates, our operating and financial results would be materially affected. In addition, we expect that a higher sales returns allowance will be recorded in the future for any other new products that we introduce until such products achieve market acceptance.

Legal contingencies: We are subject to lawsuits, investigations and claims arising out of the normal conduct of our business. While the outcome of legal proceedings cannot be predicted with certainty, loss provisions arising from such matters will be recorded

when a loss outcome is probable and can be reasonably estimated, to the extent not provided for through insurance or otherwise. At present, we have not been able to determine the probability of a loss outcome in any of the litigation to which we are currently subject. Accordingly, we have not recorded any loss provisions related to such litigation.

Results Of Operations For The Year Ended December 31, 2003 Compared To The Year Ended December 31, 2002

Certain information is set forth below for our operations expressed in dollars and as a percentage of net sales for the periods indicated:

	YEARS ENDED DECEMBER 31,			
	2003		**2002**	
Net sales	$43,496	100%	$23,548	100%
Cost of sales	13,454	31	6,752	29
Gross profit	30,042	69	16,796	71
Operating expenses	21,642	50	15,544	66
Research and development	2,557	6	294	1
Income (loss) from operations	5,843	13	958	4
Interest and other income - net	175	—	681	3
Interest expense	247	—	592	3

Income before income taxes	5,771	13	1,047	4
Provision (benefit) for income taxes	2,427	5	(3,710)	(16)
Net Income	$3,344	8%	$4,757	20%

Net Sales.

Net sales for 2003 increased to approximately $43.5 million, or 85% above net sales in 2002. Approximately one-half of the $19.9 million increase in net sales was attributable to increases in sales of Zicam Cold Remedy nasal gel products, particularly the swab products; approximately 35% of the increase was due to the three new Zicam Cold Remedy oral products introduced in 2003; and the remainder of the increase was due to increased sales of Zicam Extreme Congestion Relief. Sales of Zicam Cold Remedy nasal swab products increased due to the greater distribution and availability of supply in 2003 and a severe cold season. Zicam Extreme Congestion Relief sales increased due to greater retail distribution of the product in 2003. Sales of all of the products increased due to greater brand awareness resulting from our increased marketing efforts .

On average, our top 15 customers, which account for approximately 85% of our sales, carried six of our 10 products in 2003 compared to three of our seven products in 2002. We expect to expand the distribution of our existing products in 2004. Our principal sales focus is to secure additional retail acceptance, particularly among the major national drug, food and mass market retailers of all 10 of our

products. We expect sales increases in future periods from continued, albeit lower, growth rates for our existing 10 products and from the sale of new products that we plan to introduce in 2004 and future years.

We ended the year with a backlog in orders of $0.4 million for our adult swab product. In anticipation of year end demand, we built inventory of adult swab products starting in April 2003, but it was not sufficient as demand for all of our products, including the swab products, spiked in December 2003 due to the severe cold season. In February 2004, we began shipping our new swab product, while we also continued to ship our old swab product. As a result, we have eliminated the backlog for our adult swab product that existed in December 2003 and continued through February 2004. We will continue to ship the old swab product through the end of March 2004. We believe the new swab product can be produced at a higher rate than was possible for the old swab product and consequently we anticipate being able to avoid swab backlog issues in the 2004-2005 cold season.

Cost of Sales

The cost of sales for 2003 increased approximately $6.7 million or 99% over 2002. The increase was primarily due to an 80% increase in unit sales. The higher per unit cost of the swab products, including the higher cost agreed to in our previously announced settlement with Innovative Swab Technologies, the manufacturer of the old swab product, contributed to the increase in cost of sales. We expect that the cost of the new swab

product that we introduced in the first quarter of 2004 will result in a lower per unit cost of that product in the future.

Gross Profit

Gross profit for 2003 increased to approximately $30.0 million, or 79% above the 2002 level, due to the higher sales level. Offsetting the higher sales was the higher unit cost of sales, primarily due to the higher cost of the swab products, which is reflected in a decrease in gross profit percentage of sales to 69% in 2003 from 71% in 2002.

Operating Expenses

Operating expenses increased from approximately $15.5 million in 2002 to $21.6 million in 2003. The increase is largely due to higher advertising expense ($11.7 million in 2003 compared to $7.7 million in 2002), higher sales commission expense of $1.4 million related to the increase in sales, and higher labor costs of $0.8 million. We believe that expense levels in future periods will be primarily affected by the timing and amount of advertising expenses and costs associated with new product introductions. Also, as a result of the recent litigation against the Company described in more detail in Item 3 of this Annual Report on Form 10-K, we expect our insurance costs will increase when our product liability insurance policy is up for renewal in April 2004.

Research and Development

Research and development expense amounted to $2.6 million for 2003 compared to $294,000 for 2002, reflecting costs associated with the three new Zicam products that were introduced in 2003, development

cost of the new swab product, and research expense of product concepts that we expect to introduce in 2004 and beyond. We expect to continue to invest approximately 6% of net sales in research and development activities in order to continue to introduce new products in the future.

Interest and Other Income — Net

Interest and other income for 2003 amounted to approximately $175,000 or approximately $506,000 less than the 2002 level. Approximately $300,000 of the decrease is due to a decline in royalty income associated with a gum product marketed by Wrigley and $200,000 is due to a decrease in interest income from a lower invested cash balance.

Interest Expense

Interest expense decreased to approximately $247,000 for 2003 from approximately $592,000 in 2002. The decrease is entirely attributable to the repayment of the debt incurred with our acquisition of the 40% interest in Zicam, LLC in December 2001. We currently have no debt outstanding.

Income (Loss) From Continuing Operations Before Income Tax and Minority Interest

Our income before income taxes and minority interest in 2003 was approximately $5.8 million, an increase of approximately $4.7 million from the $1.0 million reported for 2002. The increase is due to a higher gross profit resulting from higher net sales. We expect that net income in future periods will be significantly impacted by the success of our 10 current products, new product introductions (including new products that we plan to introduce in 2004) and year-over-year changes in our advertising

and research and development budgets.

Provision For Income Tax Expense

Due to the income we recorded in 2002 and our expectation of net income in future periods, we concluded that, more likely than not, we will be able to utilize the accumulated tax loss carry-forward that had been generated in prior years but not reflected as an asset. Based on this determination, we recorded a decrease in the provision for income taxes of almost $3.4 million in 2002. The income tax expense in 2003 reflects a full provision for income tax expenses at our combined federal and state tax rates.

Results Of Operations For The Year Ended December 31, 2002 Compared To The Year Ended December 31, 2001

Certain information is set forth below for our operations expressed in dollars and as a percentage of net sales for the periods indicated:

	YEARS ENDED DECEMBER 31,			
	2002		2001	
Net sales	$23,548	100%	$ 16,072	100%
Cost of sales	6,752	29	4,215	26
Gross profit	16,796	71	11,857	74
Operating expenses	15,544	66	16,964	106
Research and development	294	1	716	4
Income (loss) from operations	958	4	(5,823)	(36)

Interest and other income – net	681	3	174	1
Interest expense	592	3	163	1
Income (loss) before provision (benefit) income taxes and minority interest	1,047	4	(5,812)	(36)
Provision for income taxes	(3,710)	(16)	—	—
Minority interest	—	—	1,013	6
Net income (loss) from continuing operations	4,757	20%	$ (4,799)	(30) %

Net Sales

Net sales for 2002 increased to approximately $23.5 million, or 47% above the 2001 sales level. Approximately one third of the $7.5 million increase in net sales is attributable to increases in sales of Zicam Cold Remedy and Allergy Relief, and the remaining two-thirds to sales of the five new Zicam products introduced in late 2002. Sales of Zicam Cold Remedy and Allergy Relief increased due primarily to increased sales to end-use customers, and additionally, with respect to sales of the Cold Remedy product, to the addition of sales to two major club warehouse outlets.

We introduced five new Zicam products in the third quarter of 2002: Cold Remedy Swabs, Cold Remedy Swabs — Kids Size, Extreme Congestion Relief, Sinus Relief and Nasal Moisturizer. The swab products in December 2002 were in a back order situation due to the inability of our supplier to

increase production, and to higher than expected demand for the adult swab product.

Cost of Sales

The cost of sales for 2002 increased approximately $2.5 million or 60% over 2001. The increase was primarily due to a 45% increase in unit sales. The higher per unit cost of the swab products and premium production cost associated with the two swab products contributed to the increase in cost of sales. A decrease in manufacturing costs of Zicam Cold Remedy and Zicam Allergy Relief partially offset this increase from the swab products.

Gross Profit

Gross profit for 2002 increased to approximately $16.8 million, or 42% above the 2001 level, due to the higher sales level. Offsetting the higher sales was the higher unit cost of sales, primarily due to the new swab products, which is reflected in a decrease in gross profit percentage of sales to 71% in 2002 from 74% in 2001.

Operating Expenses

Operating expenses decreased from approximately $17.0 million in 2001 to $15.5 million in 2002. The decrease is largely due to the settlement and legal expenses of $2.0 million that we incurred in 2001 related to a patent infringement lawsuit filed against the Company by The Quigley Corporation. Our royalty obligations to Quigley, which formed part of the settlement, ended in March 2002. A decrease in advertising and public relations expenses of approximately $0.6 million between the two years also contributed to our lower operating expenses in 2002. Offsetting these

decreases were increased sales commission expense of $252,000 related to the higher level of sales, an increase of quality control expenses primarily due to the new product analysis, an increase in total labor expense of $223,000, higher rent expense of $169,000 reflecting a full year at our new corporate office location and higher depreciation and amortization of $141,000.

Research and Development

Research and development expense amounted to $294,000 for 2002, reflecting costs associated with the five new Zicam products that were introduced in the year. Expenses in 2001 primarily reflect costs associated with our nicotine gum development which we undertook in conjunction with Swedish Match AB ("Swedish Match"). This development was terminated in the third quarter of 2001 following our exit from the gum business.

Interest and Other Income — Net

Interest and other income for 2002 amounted to approximately $681,000 or approximately $507,000 above 2001. Approximately $391,000 of the 2002 amount is royalty income and the remainder is largely interest income on our invested cash. Virtually all of the 2001 income was interest income reduced by a $250,000 write-down of an investment in a company that Matrixx had evaluated and rejected as a possible acquisition candidate.

Our interest income is largely due to the Company's invested cash position arising from the sale of our gum business in July 2001 to Wrigley, reduced in 2002 by payments made in conjunction with our acquisition of the remaining 40% interest in Zicam, LLC.

Royalty income is from a dental gum product sold by Wrigley. We entered into the royalty agreement with Wrigley in conjunction with the sale of our gum assets in July 2001.

Interest Expense

Interest expense increased to approximately $592,000 for 2002 from approximately $163,000 in 2001. The increase is entirely attributable to imputed interest accrued under the note that we issued to Zensano, Inc. (now Zengen, Inc.) in connection with our acquisition of Zensano's 40% interest in Zicam, LLC in December 2001.

Income (Loss) From Continuing Operations Before Income Tax and Minority Interest

Our income before income taxes and minority interest in 2002 was approximately $1.0 million, an increase of more than $6.8 million from the net loss of $5.8 million reported for 2001. The increase is due to a higher gross profit resulting from higher net sales and a decrease in operating expenses.

Provision For Income Tax Expense

Due to the income we recorded in 2002 and our expectation of net income in future periods, we concluded that, more likely than not, we will be able to utilize the accumulated tax loss carry-forward that had been generated in prior years but not reflected as an asset. Based on this determination, we recorded a decrease in the provision for income taxes of almost $3.4 million in 2002. Income tax expense was further reduced in the period by an income tax refund of approximately $325,000 related to a change in tax laws in 2002.

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CAUTIONARY STATEMENT REGARDING FORWARD LOOKING STATEMENTS AND RISK FACTORS

Forward Looking Statements

This Form 10-K, including documents incorporated herein by reference, contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. The words "believe", "expect", "estimate", "anticipate", "intend", "may", "might", "will", "would", "could", "project" and "predict", or similar words and phrases generally identify forward-looking statements. Forward looking statements contained herein and in documents incorporated by reference herein include, but are not limited to statements regarding:

- our expectation that the manufacturer of the new swab design will be able to meet our requirements for the next cold season;
- our intention to build inventory of swab products in 2004;
- our expectation that future distribution of our three new products will increase significantly;
- our belief that continued growth of our Extreme Congestion Relief, Sinus Relief, and Nasal Moisturizer products depends on achieving wider retail distribution;
- our intention to further develop and expand our marketing efforts to expand the market presence of our existing Zicam products and our belief that such efforts will build brand awareness, trial and sales;

- our intention to develop additional gel delivery system products and other new products;
- our expectation of committing 6% of net sales to research and development efforts in 2004 and subsequent years;
- anticipated expansion into international markets for our Zicam products and our expectations that such international markets will not provide any sales or revenue impact in the near future;
- our expectation that net income in future periods will be significantly impacted by the success of our 10 current products, our future products, and year over year changes in our advertising and research and development budgets;
- our belief that our expansion of the Zicam product line will expand our support from retailers;
- our belief that our marketing efforts will continue to build brand awareness and increase product sales;
- our expectation that the trend of increasing net sales will continue;
- our belief that future Company expense levels will be primarily affected by advertising and new product development costs and that advertising expenses will be highest in the fourth and first quarters;
- our expectation that environmental compliance-related expenses will remain low for the foreseeable future;

- our intention to vigorously defend the lawsuits that have been recently filed against us based on claims of loss of or damage to sense of smell and/or taste and our belief that any liability resulting from these or other lawsuits, including any related publicity, could materially impact our financial results;
- our expectation that the cost of the new swab product will result in a lower per unit cost of the product in the future;
- our expectation as to the future expiration dates for our two United States patents, and our intention to continue to file patent and trademark applications in the United States and in jurisdictions outside the United States to protect the Company's products;
- our ongoing relationship with our product suppliers including, their ability to meet our production needs in the future;
- our having no plans to directly manufacture and store our products;
- our expectation of net income in future periods;
- the effects of interest rate changes on our financial position;
- our expectation that we will not pay dividends in the foreseeable future;
- our belief that we will not need to borrow on our credit facility; and
- our belief that our current capital resources and credit line are sufficient to fund the Company for the next 12 months.

We may make additional written or oral

forward-looking statements from time to time in filings with the Securities and Exchange Commission or in public news releases. Such additional statements may include, but not be limited to, projections of revenues, income or loss, capital expenditures, acquisitions, plans for future operations, financing needs or plans, the impact of inflation and plans relating to our products or services, as well as assumptions relating to the foregoing. Forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified. Future events and actual results could differ materially from those set forth in, contemplated by, or underlying our forward-looking statements.

Statements in this Form 10-K, including those set forth in the sections entitled "Business" and "Management's Discussion and Analysis of Financial Condition and Results of Operations", and under the subheading below entitled "Risk Factors", describe factors that could contribute to or cause actual results to differ materially from our expectations. Other such factors include (i) less than anticipated demand for our current and future products, (ii) lack of market acceptance for or uncertainties concerning the efficacy or safety of our current and future products or regulatory actions involving our products, (iii) difficulties in increasing production or maintaining sufficient inventories to meet unexpectedly high demand in the short term, including our inability to resolve product backlog and product pricing issues, (iv) financial difficulties encountered by one or more of our principal customers, (v) difficulties in obtaining additional capital for marketing, research and development,

and other expenses, and (vii) material litigation involving patent and contractual claims, product liabilities and consumer issues.

Forward-looking statements contained in this Form 10-K speak only as of the date of this Form 10-K or, in the case of any document incorporated by reference, the date of that document. We do not undertake, and we specifically disclaim any obligation, to publicly update or revise any forward-looking statement contained in this Form 10-K or in any document incorporated herein by reference to reflect changed assumptions, the occurrence of unanticipated events or changes to future operating results over time.

Risk Factors

Our new business focus means we have a limited operating history on which to assess our current and prospective performance

Although we have been in operations for a number of years, the significant change of direction and focus in our business that we made in 2001 by exiting the chewing gum business and refocusing entirely on the development, production and sale of over-the-counter pharmaceutical products presents a limited operating history upon which you may evaluate our current and prospective performance. The possibility of our future success must be considered relative to the problems, challenges, complications and delays frequently encountered in connection with the development and operation of a new business, and the development and marketing of relatively new products such as the Zicam products.

If our Zicam products do not gain widespread market

acceptance, our anticipated sales and results of operations will suffer

Although we believe that each of our products, and in particular our Zicam Cold Remedy nasal products, offer unique benefits to consumers, we cannot be certain that any of these products will achieve widespread acceptance by the market. In addition, given their recent introduction in late 2003, our three new oral Zicam products have not yet reached the level of market recognition achieved by the original Zicam Cold Remedy nasal gel pump or swab products. While we are working to increase the market presence of all of our products, we cannot be certain that demand for these products will grow. If any unanticipated problem arises concerning the efficacy or safety of any of our products, or if any of our products fails to achieve widespread market acceptance for any other reason, our operating results and prospects would be materially adversely affected.

Unanticipated problems associated with product development and commercialization could adversely affect our operating results

Our successful development of existing and new products is subject to the risks of failure and delay inherent in the development and commercialization of products based on innovative technologies. These risks include the possibilities that:

- we may experience unanticipated or otherwise negative research and development results;
- existing or proposed products may be found to be ineffective or unsafe, or may otherwise fail to receive required regulatory clearances or

approvals;

- we may find that existing or proposed products, while effective, are uneconomical to commercialize or market;
- we may be unable to produce sufficient product inventories to meet customer demand;
- existing or proposed products do not achieve broad market acceptance; or
- proprietary rights held by third parties preclude us from developing or marketing existing or proposed products.

Our inability to develop and commercialize our existing products or any new products on a timely basis and within our financial budgets could have a material adverse effect on our operating results and future prospects.

Our inability to provide scientific proof for product claims may adversely affect our sales

The marketing of our Zicam products involves claims that these products assist in reducing the duration and severity of the common cold (in the case of Zicam Cold Remedy products and controlling allergy symptoms (in the case of Zicam Allergy Relief). Under FDA and FTC rules, we are required to obtain scientific data to support any health claims we make concerning our products. Although we have neither provided nor been requested to provide any scientific data to the FDA or FTC in support of claims regarding our Zicam products, we have obtained scientific data for our products. We cannot be certain, however, that the scientific data we have obtained in support of our claims will be deemed acceptable to the FDA or FTC, should either agency

request any such data in the future. If the FDA or the FTC requests any supporting information, and we are unable to provide support that is acceptable to the FDA or the FTC, either agency could force us to stop making the claims in question or restrict us from selling the affected products.

FDA and other government regulation may restrict our ability to sell our products

We are subject to various federal, state and local laws and regulations affecting our business. Our Zicam products are subject to regulation by the FDA, including regulations with respect to labeling of products, approval of ingredients in products, claims made regarding the products, and disclosure of product ingredients. If we do not comply with these regulations, the FDA could force us to stop selling the affected products or require us to incur substantial costs in adopting measures to maintain compliance with these regulations. Our advertising claims regarding our products are subject to the jurisdiction of the FTC as well as the FDA. In both cases we are required to obtain scientific data to support any advertising or labeling health claims we make concerning our products, although no pre-clearance or filing is required to be made with either agency. If we are unable to provide the required support for such claims, the FTC may stop us from making such claims or require us to stop selling the affected products.

We may fail to compete effectively, particularly against larger, more established pharmaceutical and health products companies, causing our business and operating results to suffer

The consumer health products industry is highly

competitive. We compete with companies in the United States and abroad that are engaged in the development of both traditional and innovative healthcare products. Many of these companies have much greater financial and technical resources and production and marketing capabilities than we do. As well, many of these companies have already achieved significant product acceptance and brand recognition with respect to products that compete directly with our Zicam products. Our competitors may successfully develop and market superior or less expensive products which could render our Zicam and other future products less valuable or unmarketable.

If we are unable to protect our intellectual property or if we infringe the intellectual property of others, our financial condition and future prospects could be materially harmed

We rely significantly on the protections afforded by patent and trademark registrations that we routinely seek from the U.S. Patent and Trademark Office ("USPTO") and from similar agencies in foreign countries. We cannot be certain that any patent or trademark application that we file will be approved by the USPTO or other foreign agencies. In addition, we cannot be certain that we will be able to successfully defend any trademark, trade name or patent that we hold against claims from, or use by, competitors or other third parties. No consistent policy has emerged from the USPTO or the courts regarding the breadth of claims allowed or the degree of protection afforded under biotechnology and similar patents. Our future success will depend on our ability to prevent others from infringing on our proprietary rights, as well as our ability to

operate without infringing upon the proprietary rights of others. We may be required at times to take legal action to protect our proprietary rights and, despite our best efforts, we may be sued for infringing on the patent rights of others. Patent litigation is costly and, even if we prevail, the cost of such litigation could adversely affect our financial condition. If we do not prevail, in addition to any damages we might have to pay, we could be required to stop the infringing activity or obtain a license. We cannot be certain that any required license would be available to us on acceptable terms, or at all. If we fail to obtain a license, our business might be materially adversely affected. In addition to seeking patent protection, we rely upon a combination of non-disclosure agreements, other contractual restrictions and trade secrecy laws to protect proprietary information. There can be no assurance that these steps will be adequate to prevent misappropriation of our proprietary information or that our competitors will not independently develop technology or trade secrets that compete with our proprietary information.

We may incur significant costs resulting from product liability claims

We are subject to significant liability should use or consumption of our products cause injury, illness or death. Although we carry product liability insurance, we cannot be sure that our insurance will be adequate to protect us against product liability claims or that insurance coverage will continue to be available on reasonable terms. In such regard, we may be required to structure self-insurance against product liability claims. Any substantial increase in insurance premiums and/or the costs of any such

self-insurance program would have a material adverse effect on our results of operations and financial condition. A product liability claim, such as those described above in this Report on Form 10-K, even if without merit or for which we have substantial coverage, could result in significant legal defense costs, thereby increasing our expenses and lowering our earnings. Such a claim, whether or not proven to be valid, could have a material adverse effect on our product branding and goodwill, resulting in reduced market acceptance of our products. This in turn could materially adversely affect our results of operations and financial condition.

We do not have manufacturing capabilities of our own

We currently do not have the physical or human resources to independently manufacture our Zicam products or any other products that we may develop. We currently outsource all of our product manufacturing and packaging operations and intend to continue this outsourcing for the foreseeable future. If we are unable to enter into cost-effective or otherwise suitable arrangements for manufacturing of our Zicam products or any other products, or if our third party contractors fail to adequately perform their manufacturing operations (as occurred with our old swab products), our sales and related financial results could be materially adversely affected. If, in the future, we decide to establish our own manufacturing facilities, we will require substantial additional funds and significant additional personnel to undertake such operations. We cannot be certain that such funding or a sufficient number of such qualified persons will be

available for such an undertaking.

We may continue to experience product backlogs

At the end of fiscal 2002, we had approximately $1.3 million in backlog of swab orders and at the end of fiscal 2003, we had approximately $0.4 million in backlog of swab orders. We have undertaken significant measures to remedy the manufacturing problems that led to our backlog in 2002 and 2003, including replacing our swab manufacturer and redesigning our swab product to permit higher volume production. We also intend to build a substantial inventory of swab products to reduce the likelihood of any backlog of swab products occurring in the 2004-2005 cough and cold season. However, we cannot be certain that these measures will be sufficient to prevent future backlog of these products or that other product backlogs will not occur in the future. Any such future backlogs will potentially result in higher production costs, higher freight costs to expedite shipment of raw materials and finished goods, fines from certain retailers, cancelled orders and lost opportunity costs. These in turn could materially affect our results of operations and financial condition

Our board of directors is authorized to issue shares of preferred stock that could have rights superior to our outstanding shares of common stock, and, if issued, could adversely impact the value of our common stock

Our certificate of incorporation permits our board of directors, in its sole discretion, to issue up to 2,000,000 shares of authorized but unissued preferred stock. These shares may be issued by our board without further action by our shareholders,

and may include any of the following rights (among others) as our board may determine, which rights may be superior to the rights of our outstanding common stock:

- voting rights, including the right to vote as a class on particular matters;
- preferences as to dividends and liquidation rights;
- conversion rights;
- anti-dilution protections; and
- redemption rights.

Since our board of directors has the authority to determine, from time to time, the terms of our authorized preferred stock, there is no limit on the amount of common stock that could be issuable upon conversion of any future series of preferred stock that may be issued. The rights of holders of our common stock will be subject to, and may be adversely affected by, the rights of the holders of any series of preferred stock that may be issued in the future. In addition, the market price of our common stock may be adversely affected by the issuance of any series of preferred stock with voting or other rights superior to those of our common stock. The issuance of any series of preferred stock could also have the effect of making it more difficult for a third party to acquire a majority of our outstanding common stock.

The price of our stock may continue to be volatile

The market price of our common stock, which is quoted for trading on the Nasdaq National Market, has been highly volatile and may continue to be

volatile in the future. Any or a combination of the following factors could cause the market value of our common stock to decline quickly: Operating results that differ from market expectations, negative or other unanticipated results of clinical trials or other testing, delays in product development, technological innovations or commercial product introductions by our competitors, changes in government regulations, developments concerning proprietary rights, including pending or threatened patent litigation, public concerns regarding the safety of any of our products and general economic and stock market conditions. These fluctuations have particularly affected the market prices of equity securities of small capitalization companies, like Matrixx. Often, the effect on the price of such securities is disproportionate to the operating performance of such companies. In our case, such broad market fluctuations may adversely affect our stockholders' ability to dispose of their shares of Matrixx at a price equal to or above the price at which they purchased such shares. In addition, we believe our stock price has been impacted by a sizeable short position and resulting covering by investors with a short position in our stock.

***

MATRIXX INITIATIVES, INC. AND SUBSIDIARY

(formerly Gum Tech International, Inc.)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

INDEPENDENT AUDITORS' REPORT

To the Board of Directors and Shareholders of Matrixx Initiatives, Inc.

We have audited the accompanying consolidated balance sheets of Matrixx Initiatives, Inc. and Subsidiary as of December 31, 2003 and 2002 and the related consolidated statements of operations, changes in stockholders' equity and cash flows for the years then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Matrixx Initiatives, Inc. and Subsidiary as of December 31, 2003 and 2002 and the results of their operations and their cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

Mayer Hoffman
McCann P.C.

Certified Public
Accountants

Greenwood Village, Colorado
January 23, 2004

(except for the second to last paragraph of Note 11, as to which the date is March 12, 2004)

INDEPENDENT AUDITORS' REPORT

To the Board of Directors and Shareholders of Matrixx Initiatives, Inc.

We have audited the accompanying consolidated statements of operations, changes in stockholders' equity and cash flows of Matrixx Initiatives, Inc. and Subsidiary for the year ended December 31, 2001. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the results of operations and cash flows of Matrixx Initiatives, Inc. and Subsidiary for the year ended December 31, 2001 in conformity with accounting

principles generally accepted in the United States of America.

Angell & Deering
Certified Public Accountants

Denver, Colorado
February 8, 2002

***

11. Commitments and Contingencies

Leases

The Company leases its office facilities under a long-term leasing arrangement. The following is a schedule of future minimum lease payments at December 31, 2003 under the Company's operating leases that have initial or remaining noncancellable lease terms in excess of one year, including the office lease agreement signed in January of 2004:

11. Commitments and Contingencies (Continued)

Leases (Continued)

Year Ending December 31	Facilities
2004	$112,772
2005	82,096
2006	85,371

2007	88,647
Total Minimum Lease Payments	$368,886

Rental expense charged to operations was $267,596, $256,804 and $280,838 for the years ended December 31, 2003, 2002 and 2001, respectively.

Officer Indemnification

Under the organizational documents, the Company's officers, employees, and directors are indemnified against certain liability arising out of the performance of their duties to the Company. The Company also has an insurance policy for its directors and officers to insure them against liabilities arising from the performance of their duties required by their positions with the Company. The Company's maximum exposure under these arrangements is unknown as this would involve future claims that may be made against the Company that have not yet occurred. However, based on experience, the Company expects the risk of loss to be remote.

Litigation

The Company is involved in various product liability claims and other legal proceedings that arise from time to time in the ordinary course of business. The Company does not believe any of them will have a material adverse affect on the Company's financial position. Litigation is inherently unpredictable, and excessive verdicts

do occur. Although the Company believes it has valid defenses in these matters, the Company could in the future incur judgments or enter into settlements of claims that could have a material adverse affect on the Company's financial position or results of operations in any particular period.

Among the principal matters pending to which the Company is a party are the following:

Product Liability Matters

Litigation relating to Zicam® Cold Remedy nasal gel arises from claims that the product causes the permanent loss of taste and smell, or anosmia. The Company feels that the clinical studies performed on the product are sufficient evidence to refute such claims.

As of December 31, 2003, suits involving three users of the Zicam® Cold Remedy nasal gel products had been filed in various federal and state courts. All of these suits are at a preliminary stage and the Company has not yet obtained and reviewed complete information regarding the plaintiffs and their medical conditions, and consequently, the Company is unable to fully evaluate the claims.

On March 12, 2004, the Company was served with a complaint that was filed in the Superior Court of Maricopa County, Arizona, whereby sixty-four plaintiffs alleged that the use of the Zicam® Cold Remedy nasal gel products resulted in anosmia, the loss of their sense of smell. Specific damages have not been requested and the Company has turned the lawsuit over to its

product liability insurance carrier.

The Company is actively engaged in defending these various lawsuits.

***

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized, in Phoenix, Arizona, on March 19, 2004.

MATRIXX
INITIATIVES, INC.

By: /s/ Carl J. Johnson

Carl J. Johnson

President and Chief
Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this Report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dated indicated:

Signature	Title	Date
/s/ Edward E. Faber Edward E. Faber	Chairman of the Board of Directors	March 19, 2004

/s/ Carl J. Johnson Carl J. Johnson	President, Chief Executive Officer and Director	March 19, 2004
/s/ William C. Egan William C. Egan	Director	March 19, 2004
/s/ Edward J. Walsh Edward J. Walsh	Director	March 19, 2004
/s/ L. White Matthews, III L. White Matthews, III	Director	March 19, 2004
/s/ Michael A. Zeher Michael A. Zeher	Director	March 19, 2004
/s/ William J. Hemelt William J. Hemelt	Executive Vice President, Chief Financial Officer (Principal Financial Officer & Principal Accounting	March 19, 2004

Officer),

Treasurer and
Secretary

APPENDIX E

JUDGMENT

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

James V. Siracusano,	)	
	)	
Plaintiff(s),	)	CIV-04-886-PHX-MHM
	)	
v.	)	CIV-04-1012-PHX-MHM
	)	
Matrixx Initiatives, Inc., et al.,	)	(Consolidated)
	)	
	)	**JUDGMENT**
Defendant(s).	)	

_____ **Jury Verdict**. This action came before the Court for a trial by jury. The issues have been tried and the jury has rendered its verdict.

XXX **Decision by Court**. This action came for consideration before the Court. The issues have been considered and a decision has been rendered.

IT IS ORDERED AND ADJUDGED that this Court having granted Defendants' Motion to Dismiss, Plaintiffs take nothing. This Complaint and action are hereby dismissed without prejudice. DATED at Phoenix, Arizona, this 8th day of March, 2006.

RICHARD H. WEARE
DCE/Clerk of Court

By: s/ M. Pruneau
Deputy Clerk

CIV-21 (7/94)

APPENDIX F

FDA WARNING LETTER TO MATRIXX

Inspections, Compliance, Enforcement, and Criminal Investigations

Matrixx Initiatives, Inc. AKA Zicam LLC
6/16/09

Department of Health and Human Services

Public Health Service
Food and Drug Administration

WARNING LETTER

June 16, 2009

VIA FAX & FEDEX

RETURN RECEIPT REQUESTED

William J. Hemelt, Acting President, CFO and COO
Matrixx Initiatives, Inc

8515 East Anderson Drive
Scottsdale, AZ 85255

Dear Mr. Hemelt:

This letter concerns your firm's marketing of the products Zicam Cold Remedy Nasal Gel, Zicam Cold Remedy Gel Swabs, and Zicam Cold Remedy Swabs, Kids Size.

FDA has concluded that these products may pose a serious risk to consumers who use them. Specifically, FDA has received more than 130 reports of anosmia, (loss of sense of smell, which in some cases can be long-lasting or permanent), associated with use of these products.

To protect consumers, and in light of the violations described below, we ask that within fifteen working days of receipt of this letter, you notify this office in writing of the specific steps that you have taken to correct the violations.

These products are available without a prescription, and they contain zinc gluconate (identified as zincum gluconicum on their labels) as their active ingredient. All are administered by direct application to the nasal cavity and, as described in the labeling, are intended for use in "adults and children 3 years of age and older (with adult supervision)." These products are referred to hereafter as the "Zicam Cold Remedy intranasal products."

According to the labeling accompanying the Zicam Cold Remedy intranasal products, each of these products "reduces" the "duration of the common cold" and the "severity of cold symptoms," including specifically "sore throat • stuffy nose •sneezing •

coughing • congestion." These claims make these products drugs, as defined by section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 321(g)(1), because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure or function of the body of man or other animals.

We are not aware of any data establishing that the Zicam Cold Remedy intranasal products are generally recognized as safe and effective for the uses identified in their labeling.[1] On the contrary, as described below, there is evidence that these products pose a serious safety risk to consumers. Because they are not generally recognized as safe and effective for their labeled uses, these products are new drugs, as defined by section 201(p) of the Act, 21 U.S.C. § 321(p).

Under sections 301(d) and 505(a) of the Act, 21 U.S.C. §§ 331(d) and 355(a), a new drug may not be introduced or delivered for introduction into interstate commerce unless an FDA-approved application is in effect for it. There are no approved new drug applications (NDAs) on file with FDA for any of the Zicam Cold Remedy intranasal products; you market them without FDA approval.

We recognize that the labeling for Zicam Cold Remedy intranasal products identifies them as homeopathic drug products with an active ingredient measured in homeopathic strength—Zincum Gluconicum 2X. Nothing in the Act or the regulations issued under it exempts homeopathic drugs from the new drug approval requirements. We acknowledge that many homeopathic drug products are manufactured and

distributed without FDA approval under enforcement policies set out in the FDA's Compliance Policy Guide entitled, "Conditions Under Which Homeopathic Drugs May be Marketed (CPG 7132.15)" (the CPG). The enforcement discretion set forth in the CPG is not unlimited, however. The CPG states that it "delineates those conditions under which homeopathic drugs may *ordinarily* be marketed in the U.S." (emphasis added) The qualifying word "ordinarily" indicates that the CPG specifically contemplates that there may be circumstances where a product that otherwise may meet the conditions set forth in the CPG may nevertheless be subject to enforcement action.

A significant and growing body of evidence substantiates that the Zicam Cold Remedy intranasal products may pose a serious risk to consumers who use them. Specifically, FDA has received more than 130 reports of anosmia (loss of sense of smell, which in some cases can be long-lasting or permanent),associated with use of these products; some individuals also report loss of sense of taste.[2] By comparison, FDA has received few reports of anosmia associated with other widely-used intranasal products for treatment of the common cold that are marketed subject to approved NDAs or according to an OTC drug monograph. Further, there is evidence in the published scientific literature that various salts of zinc can damage olfactory function in animals and humans.

A homeopathic drug product marketed without an approved NDA is not subject to the enforcement discretion set forth in the CPG when there is evidence of a safety risk associated with the product, as is the case for the Zicam Cold Remedy intranasal

products. Under these circumstances, the Agency enforces the Act's new drug approval requirement, a provision that is essential to protect the public health by holding firms responsible for demonstrating, based on adequate and well-controlled clinical investigations, that a product is safe and effective for each of its intended uses before marketing it. Therefore, an approved NDA is required for the Zicam Cold Remedy intranasal products, regardless of their homeopathic status. Your introduction of the Zicam Cold Remedy intranasal products into interstate commerce, without an approved application, violates sections 301(d) and 505(a) of the Act, 21 U.S.C. §§ 331(d) and 355(a).

Additionally, Zicam Cold Remedy intranasal products are misbranded under section 502(f)(2) of the Act, 21 U.S.C. § 352(f)(2), because their labeling does not bear adequate warnings regarding the risk of anosmia associated with the product. In light of this failure to bear adequate warnings, these products are also misbranded under section 502(a) of the Act, 21 U.S.C. § 352(a), taking into account the considerations set forth in section 201(n) of the Act, 21 U.S.C. § 321(n).

The issues and violations cited in this letter are not intended to be an all-inclusive statement of violations that exist in connection with your products. You are responsible for investigating and determining the causes of the violations identified above and for preventing their recurrence or the occurrence of other violations. It is your responsibility to assure that your firm complies with all requirements of federal law and FDA regulations. A description of the new drug approval

process can be found on FDA's internet website at http://www.fda.gov/cder/regulatory/applications/default.htm. Any questions you may have regarding this process should be directed to the Food and Drug Administration, Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, 5600 Fishers Lane, Rockville, Maryland 20857.

You should take prompt action to correct the violations cited in this letter. Failure to promptly correct these violations may result in legal action without further notice, including, without limitation, seizure and injunction. Other federal agencies may take this Warning Letter into account when considering the award of contracts.

Within fifteen working days of receipt of this letter, please notify this office in writing of the specific steps that you have taken to correct violations. Include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. If you cannot complete corrective action within fifteen working days, state the reason for the delay and the time within which you will complete the corrections. Furthermore, please advise this office what actions you will take to address product that you have already distributed.

In addition to the reports FDA has received directly from consumers, the agency is aware that Matrixx appears to have more than 800 reports related to loss of sense of smell associatedwith Zicam Cold Remedy intranasal products. Please contact

Elisabeth Walther at the contact information below to arrange submission of all reports you have related to loss of sense of smell associated with Zicam Cold Remedy intranasal products. Please indicate which of these reports have been previously submitted to FDA.

Additionally, if another firm or firms manufacture the products identified above, your reply should include the name and address of all such firms. If the firm from which you receive the products is not the manufacturer, please include the name of your supplier in addition to the manufacturer. Address your reply to the U.S. Food and Drug Administration, Center for Drug Evaluation and Research, Office of Compliance, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, **Attention: Elisabeth Walther, Pharmacist**.

Sincerely,

Deborah M. Autor, Esq.
Director
Office of Compliance
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

---

[1] Under the Agency's OTC drug review, FDA has adopted a final monograph that establishes conditions under which OTC cold, cough, allergy, bronchodilator, and anti-asthmatic drug products, in forms suitable for oral, inhalant, or topical administration, are generally recognized as safe and effective. 21 CFR Part 341 (the OTC Cold Cough monograph). This final monograph covers products intended to treat the same conditions for which Zicam is labeled (i.e., treatment of the common cold and cold symptoms). Although homeopathic drugs are excluded from the OTC drug review (37

F.R. 9464, 9466 (May 11, 1972)), we note that the OTC Cold Cough monograph does not include any products in any dosage form containing zinc or any salt of zinc as their active ingredient.

[2] We note that loss of sense of smell can have serious consequences. For example, patients with anosmia may not be able to detect the smell of a gas leak, smoke, or spoiled food. Loss of sense of taste can have a major impact on an individual's quality of life.

PETITIONER'S BRIEF

Supreme Court, U.S.
FILED
AUG 2 0 2010
OFFICE OF THE CLERK

No. 09-1156

IN THE

Supreme Court of the United States

MATRIXX INITIATIVES, INC., ET AL.,
Petitioners,

v.

JAMES SIRACUSANO AND NECA-IBEW PENSION FUND,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

BRIEF FOR PETITIONERS

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Attorneys for Petitioners

880/B

QUESTION PRESENTED

Respondents filed suit under § 10(b) of the Securities Exchange Act of 1934 and Securities and Exchange Commission ("SEC") Rule 10b-5, alleging that petitioners committed securities fraud by failing to disclose "adverse event" reports—i.e., reports by users of a drug that they experienced an adverse event after using the drug. The First, Second, and Third Circuits have held that drug companies have no duty to disclose adverse event reports until the reports provide statistically significant evidence that the adverse events may be caused by, and are not simply randomly associated with, a drug's use. Expressly disagreeing with those decisions, the Ninth Circuit below rejected a statistical significance standard and allowed the case to proceed despite the lack of any allegation that the undisclosed adverse event reports were statistically significant. The question presented is:

Whether a plaintiff can state a claim under § 10(b) of the Securities Exchange Act and SEC Rule 10b-5 based on a pharmaceutical company's nondisclosure of adverse event reports even though the reports are not alleged to be statistically significant.

PARTIES TO THE PROCEEDING

Petitioners are Matrixx Initiatives, Inc., Carl Johnson, William Hemelt, and Timothy Clarot, defendants-appellees below.

Respondents are James Siracusano, named plaintiff and appellant below, and the NECA-IBEW Pension Fund, lead plaintiff and appellant below, on behalf of themselves and all others similarly situated who purchased Matrixx securities between October 22, 2003, and February 6, 2004.

RULE 29.6 DISCLOSURE

Matrixx Initiatives, Inc. has no parent corporation and no person or publicly traded corporation owns more than 10% of Matrixx's stock.

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IN THE

Supreme Court of the United States

No. 09-1156

MATRIXX INITIATIVES, INC., ET AL.,
Petitioners,

v.

JAMES SIRACUSANO AND NECA-IBEW PENSION FUND,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

BRIEF FOR PETITIONERS

OPINIONS BELOW

The decision of the court of appeals is reported at 585 F.3d 1167 and is reprinted in the Appendix to the Petition ("Pet. App.") at 1a-34a. The district court's opinion is available at 2005 WL 3970117 and is reprinted at Pet. App. 35a-54a.

JURISDICTION

The court of appeals issued its decision on October 28, 2009, and denied a petition for rehearing and rehearing *en banc* on December 23, 2009. Pet. App. 55a-56a. The petition was filed on March 23, 2010, and granted on June 14, 2010. The Court's jurisdiction rests on 28 U.S.C. § 1254(1).

STATUTES AND REGULATION INVOLVED

The relevant provisions of the Securities Exchange Act of 1934, 15 U.S.C. § 78j(b), and the Private Securities Litigation Reform Act of 1995 ("PSLRA"), 15 U.S.C. § 78u-4(b)(2), and Securities and Exchange Commission ("SEC") Rule 10b-5 are reproduced at Pet. App. 57a-58a.

STATEMENT OF THE CASE

A. Statutory Background

To state a claim of fraud under § 10(b) of the Securities Exchange Act and SEC Rule 10b-5, a plaintiff must allege (1) the misrepresentation or omission of a material fact; (2) made with scienter; (3) in connection with the purchase or sale of a security; (4) on which the plaintiff relied; and (5) that was causally connected to (6) the plaintiff's loss. *See Stoneridge Inv. Partners, LLC v. Scientific-Atlanta, Inc.*, 552 U.S. 148, 157 (2008). This case implicates two of those elements: materiality and scienter.

1. *Materiality*

A statement can be "false or incomplete" and yet not actionable under § 10(b) "if the misrepresented fact is otherwise insignificant." *Basic Inc. v. Levinson*, 485 U.S. 224, 238 (1988). "The plain language of Rule 10b-5 . . . requires any successful securities-fraud suit to allege a fact that is both untrue *and* material." *Greenhouse v. MCG Capital Corp.*, 392 F.3d 650, 656 (4th Cir. 2004). A fact is material when there is "'a substantial likelihood'" that a reasonable investor would view it as "'significantly alter[ing] the "total mix" of information made avail-

able.'" *Basic*, 485 U.S. at 232 (quoting *TSC Indus., Inc. v. Northway, Inc.*, 426 U.S. 438, 449 (1976)).

The materiality requirement serves to "filter out essentially useless information that a reasonable investor would not consider significant." *Id.* at 234. Indeed, "[s]ome information is of such dubious significance that insistence on its disclosure may accomplish more harm than good." *TSC Indus.*, 426 U.S. at 448. The materiality filter helps ensure that corporations do not "bury the shareholders in an avalanche of trivial information—a result that is hardly conducive to informed decisionmaking." *Id.* at 448-49; *see also Basic*, 485 U.S. at 231. When a complaint alleges that a statement is misleading because a material fact was omitted, the complaint must "specify the reason or reasons why" the omission makes the statement misleading. 15 U.S.C. § 78u-4(b)(1)(B).

2. *Scienter*

A private plaintiff asserting a § 10(b) action must also establish that the defendant acted with "scienter," which "refers to a mental state embracing intent to deceive, manipulate, or defraud." *Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 193 n.12 (1976). The scienter element requires a plaintiff to show that the defendant engaged in "intentional or willful conduct designed to deceive or defraud investors by controlling or artificially affecting the price of securities." *Id.* at 199.

To satisfy this element at the pleading stage, a complaint must satisfy demanding requirements. The Private Securities Litigation Reform Act of 1995 ("PSLRA"), Pub. L. No. 106-47, 109 Stat. 737 (codi-

fied at 15 U.S.C. §§ 77z-1 and 78u-4), was enacted to curb "abusive litigation by private parties," and one of its key "control measures" is a heightened pleading requirement for scienter. *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 313 (2007). To survive a motion to dismiss, a complaint not only must "state with particularity" the facts establishing scienter, but those facts must "giv[e] rise to a strong inference" that the defendant intended to deceive investors. 15 U.S.C. § 78u-4(b)(2). A "strong inference" of scienter means an inference "at least as compelling as any opposing inference one could draw from the facts alleged." *Tellabs*, 551 U.S. at 324. The reviewing court thus must consider—on the basis of the complaint as a whole, including all documents incorporated by reference, *id.* at 322-23, as well as the court's own "judicial experience and common sense," *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1950 (2009)—whether there are "nonculpable explanations for the defendant's conduct" that are more likely than the plaintiff's explanation, *Tellabs*, 551 U.S. at 324. If so, the suit cannot proceed, because the inference of scienter is not "*at least as likely* as any plausible opposing inference." *Id.* at 328.

B. Factual Background

1. Petitioner Matrixx Initiatives, Inc. ("Matrixx") is a pharmaceutical company that sells cold remedy products through its wholly owned subsidiary, Zicam, LLC. Pet. App. 2a. One of Matrixx's main products is Zicam Cold Remedy ("Zicam"), a homeopathic remedy that has been clinically proven to reduce the duration and severity of the common cold. J.A. 212a.

Zicam comes in a variety of forms. The nasal spray and gel swab forms at issue here were marketed during the Class Period. *Id.*; *see also* Pet. App. 4a. The active ingredient in Zicam is zinc gluconate. *See* Pet. App. 4a. Prior to the events at issue here, Matrixx conducted two published double-blind, placebo-controlled, randomized clinical studies of intranasal application of zinc gluconate. J.A. 193a-94a. In both studies, "[t]he overall incidence of adverse events associated with zinc gluconate treatment was extremely low, with no statistically significant difference between the adverse event rates for the treated and placebo subsets." *Id.* at 194a.

2. Respondents allege that, starting in December 1999, petitioners began to receive isolated reports that some consumers were experiencing anosmia, or loss of smell, following use of Zicam. According to respondents:

- Matrixx was first advised by Dr. Alan Hirsch in December 1999 that he was aware of "at least one" user who complained of anosmia after using the product. J.A. 67a-68a (Compl. ¶ 25).
- In September 2002, petitioner Timothy Clarot, Matrixx's Vice President and Director of Research and Development, corresponded with Dr. Miriam Linschoten, a doctor at the University of Colorado Health Sciences Center, after one of Linschoten's patients contacted Matrixx to complain of anosmia. J.A. 68a (Compl. ¶ 26).
- In September 2003, Dr. Bruce Jafek, also at the University of Colorado, prepared a poster

presentation with Dr. Linschoten and another colleague, claiming ten reports of anosmia after using Zicam to treat a cold. J.A. 69a-70a (Compl. ¶ 28).

- By February 6, 2004, four lawsuits, with a total of nine plaintiffs, had been filed claiming anosmia caused by Zicam use. J.A. 87a-92a (Compl. ¶ 49); Pet. App. 25a-26a.

Because the complaint does not identify any user by name, it is possible, even likely, that some of these reports are "double counted." For instance, some or all of the nine plaintiffs were likely among the ten unnamed patients described in Jafek's poster presentation, especially given that Jafek was an expert for plaintiffs in some of the cases. *See, e.g.*, *Sutherland v. Matrixx Initiatives, Inc.*, 2006 U.S. Dist. LEXIS 96652 (N.D. Ala. Nov. 7, 2006). The total number of specific reports identified in the complaint as made during the class period is thus either 12 if the personal-injury plaintiffs are not treated separately—and they should not be, given the requirements for pleading with specificity—or 21 if they are.[1]

3. Matrixx attempted to obtain more information about the user complaints reported by Linschoten and Jafek. In the course of her conversation with Clarot, Linschoten allegedly referred to polio studies from the 1930s concerning the intranasal application of zinc sulfate—a compound different from the zinc gluconate used in Zicam. J.A. 68a-69a

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[1] Respondents count the reports slightly differently and produce a figure of 23. Opp. to Pet. for Cert. 20. The exact figure is irrelevant for the reasons explained in this brief.

(Compl. ¶¶ 26-27).[2] Clarot advised Linschoten that Matrixx had already hired a consultant to examine the issue. Clarot also inquired whether she would be willing to participate in animal studies examining the effects of zinc gluconate. J.A. 69a (Compl. ¶ 27). Linschoten declined. *Id.*

Matrixx also attempted to obtain more information from Jafek about the incident reports he was claiming. On September 12, 2003, after becoming aware of Jafek's forthcoming poster presentation, Matrixx wrote him a letter explaining that it took very seriously any questions about Zicam's safety and was "very much interested in learning more about the adverse reports included in [the] presentation." J.A. 117a-18a; *see also id.* at 118a ("Prior to your presentation next week, we would very much appreciate the opportunity to learn more about the reports you will be describing and the basis for linking them with the use of zinc nasal products."). Matrixx's letter also advised Jafek that he lacked permission to use the trademark "Zicam" in his presen-

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[2] In subsequent products liability lawsuits, the opinions of plaintiffs' experts (including Jafek) on the effects of Zicam relied heavily on the old polio studies, and courts repeatedly rejected those opinions as unreliable. *See, e.g., Benkwith v. Matrixx Initiatives, Inc.*, 467 F. Supp. 2d 1316, 1327 (M.D. Ala. 2006); *Evans v. Matrixx Initiatives, Inc.*, 2009 WL 2914252, at *10 (M.D. Fla. Feb. 18, 2009); *Lusch v. Matrixx Initiatives, Inc.*, 2007 U.S. Dist. LEXIS 72068, at *11-12 (D. Or. Sept. 25, 2007); *O'Hanlon v. Matrixx Initiatives, Inc.*, 2007 U.S. Dist. LEXIS 65655, at *7 & n.5 (C.D. Cal. Jan. 3, 2007); *Rose v. Matrixx Initiatives, Inc.*, 2009 WL 902311, at *8-9 (W.D. Tenn. Mar. 31, 2009); *Sutherland*, 2006 U.S. Dist. LEXIS 96652, at *26-27; *Wyatt v. Matrixx Initiatives, Inc.*, 2007 U.S. Dist. LEXIS 67986, at *9-10 (N.D. Ala. Mar. 30, 2007).

tation. J.A. 118a. The complaint includes no indication that Jafek ever provided Matrixx any additional information about the reports he was claiming. *Id.* 58a-111a.

Jafek presented the poster later in September 2003, but did not refer to Zicam by name. J.A. 70a (Compl. ¶ 29).

4. On January 30, 2004, the *Dow Jones Newswire* reported that three lawsuits had been filed against Matrixx. The report caused a dip in price of Matrixx shares. J.A. 62a, 79a-80a (Compl. ¶¶ 6, 40-41); *id.* at 188a-92a (Longo Decl. Ex. 7).

In response to the *Dow Jones* report, Matrixx issued a press release on February 2, 2004, stating its belief that "statements alleging that intranasal Zicam products cause anosmia (loss of smell) are completely unfounded and misleading." J.A. 77a-78a (Compl. ¶ 38); *id.* at 193a-95a (Longo Decl. Ex. 8). The press release explained that Matrixx had not received any reports of anosmia during the premarket clinical trials. *Id.* at 193a-94a. Matrixx further explained that because anosmia is frequently caused by the common cold—the very condition Zicam is used to treat—"the population most likely to use the cold remedy products is already at [an] increased risk of developing anosmia," which could lead users to report an erroneous association between use of Zicam and anosmia. *Id.* at 78a (Compl. ¶ 38).[3] The stock price normalized after Matrixx is-

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[3] This phenomenon is known as "confounding by indication," where a known cause of the reported event is the very condition for which the drug is indicated, which makes establishing causation very difficult. "When a drug is claimed to

sued the press release. *Id.* at 80a (Compl. ¶ 41).

On February 6, 2004, however, Jafek appeared in a *Good Morning America* segment and affirmatively declared that Zicam causes anosmia. J.A. 80a-81a (Compl. ¶¶ 42-43); *id.* at 196a-200a (Longo Decl. Ex. 9). The *Good Morning America* feature also mentioned the products liability suits that had been filed against Matrixx. *Id.* at 199a-200a. The day the program aired, Matrixx's stock price dropped from its previous day close of $13.04 to $9.94 at the close of trading on February 6, despite Matrixx's issuance of another press release that day reiterating the facts asserted in its previous release. *Id.* 81a-82a (Compl. ¶¶ 43-44). That day—February 6, 2004—marked the end of the class period.[4]

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cause the very symptoms for which it is a designated treatment, determining the direction of causation is difficult at best." *Robinson v. McNeil Consumer Healthcare*, 2010 WL 3156548, at *5 (7th Cir. Aug. 11, 2010); *see* FDA, Center for Drug Evaluation and Research, Guidance for Industry: Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment ("Good Pharmacovigilance") 7, 13 (Mar. 2005) ("Confounding by indication is one example of an important concern in performing a pharmacoepidemiologic study."), *available at* http://www.fda.gov/OHRMS/DOCKETS/98fr/04d-0189-gdl 0002.pdf.; *see generally* Michael D. Green et al., Reference Guide on Epidemiology, in Federal Judicial Center, Reference Manual on Scientific Evidence ("Reference Guide on Epidemiology") 369-70 (2d ed. 2000) (discussing problem of confounding).

[4] The complaint also cites a Matrixx 8-K issued on February 19, 2004—*after* the close of the Class Period—which stated that Matrixx "had convened a two-day meeting of physicians and scientists to review current information on smell disorders," and that "the opinion of the panel" was that "there is insufficient evidence at this time to determine if zinc gluconate, when used as recommended, affects a person's ability to smell."

C. Proceedings Below

1. Respondents filed suit on May 19, 2004, alleging that petitioners' omission of the aforementioned adverse event reports ("AERs") caused company statements about business growth and Zicam safety to be false and misleading. Respondents claimed that failure to disclose the AERs led to investment losses suffered on February 6, 2004, after Jafek announced on *Good Morning America* that Zicam causes anosmia.

Respondents allege that between October 23, 2003, and February 6, 2004 (the "Class Period"), petitioners "touted the growth of business" based primarily on "the increased success of [the] Zicam cold remedies" (J.A. 61a (Compl. ¶ 5)) and made several statements concerning the safety of Zicam in response to media reports and statements by Jafek (*id.* 62a-64a (Compl. ¶¶ 7, 9); *see id.* at 71a-79a (Compl. ¶¶ 32, 33, 35, 37, 39)). These Zicam-related business-growth and safety statements were false and misleading, respondents say, because petitioners failed to disclose that "large numbers [sic] of Zicam users had lost their sense of smell." Opp. to Pet. for Cert. 12; *see* J.A. 64a (Compl. ¶ 9).[5]

J.A. 82a (Compl. ¶¶ 45-46); *id.* at 205a-07a (Longo Decl. Ex. 11). The statement has no bearing on Matrixx's statements or scienter during the Class Period.

[5] Respondents also alleged that a statement made in November 2003 that Matrixx could "incur significant costs resulting from product liability lawsuits," was misleading because one lawsuit had already been filed. J.A. 75a (Compl. ¶ 35). That allegation is not directly pertinent to the question before this Court, *see infra* note 25, except insofar as the lawsuit was the effective equivalent of an isolated incident report petition-

Respondents further allege that petitioners acted with scienter because they "were aware since at least September 2003, that numerous users of their Zicam product had experienced a rare condition known as anosmia or loss of smell." J.A. 101a (Compl. ¶ 64). Respondents also assert that petitioners' statement to Jafek that he lacked permission to use the trademarks Matrixx and Zicam, while wholly accurate, nevertheless demonstrated a willful intent to deceive. *Id.*

2. Matrixx moved to dismiss the complaint for failure to state a claim for securities fraud under § 10(b) and Rule 10b-5. The district court granted the motion, concluding that respondents had failed to sufficiently plead the elements of materiality and scienter. *See* Pet. App. B.

As to materiality, the district court invoked the statistical significance requirement enunciated in *In re Carter-Wallace, Inc. Securities Litigation (Carter-Wallace II)*, 220 F.3d 36 (2d Cir. 2000), to hold that respondents had failed to allege "the reliability and accuracy of the user complaints," and that "[e]ven if there were data as to the reliability" of the complaints, "12 user complaints is not statistically significant." Pet. App. 50a. Accordingly, the district court concluded that nondisclosure of the reports was not a "material omission." *Id.*

The court further held that respondents had failed to plead scienter adequately because they did not plead facts establishing that petitioners "*knew*

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ers were obliged to disclose under respondents' materiality theory.

there was a definitive and statistically significant link between Zicam and anosmia *during the Class Period* that was sufficiently serious and frequent to affect future earnings." *Id.* at 54a (internal quotation marks omitted).

The court granted respondents leave to cure these defects and plead additional facts concerning the materiality of the omitted AERs or concerning petitioners' willful intent to deceive. Respondents chose instead to appeal.

3. The court of appeals reversed. *See* Pet. App. A. The court rejected the *Carter-Wallace* statistical-significance requirement, *see* Pet. App. 34a, and held that respondents had sufficiently pled materiality by alleging the nondisclosure of the anosmia-related AERs, *id.* at 26a, 34a. It further held that respondents had adequately pled scienter, concluding that the allegations of nondisclosure, combined with the statement that Jafek lacked permission to use Matrixx's trademarks, gave rise to an inference that petitioners acted "intentionally or with deliberate recklessness" that was "at least as compelling as any plausible nonculpable explanation." *Id.* at 34a.[6]

This Court granted certiorari.

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[6] At no point during the class period did the FDA issue a warning letter or otherwise publicly question Zicam's safety. On June 16, 2009, while the appeal was pending in the Ninth Circuit, and more than five years after the close of the Class Period, the FDA issued a warning letter stating that Zicam "may pose a serious risk to consumers." J.A. 268a. Matrixx disputes the claims in the letter, but, in any event, it has no bearing on the events that occurred more than five years earlier.

SUMMARY OF THE ARGUMENT

I. Respondents' complaint does not plead facts establishing that the omitted AERs identified by respondents were material under § 10(b) or Rule 10b-5.

A. The reports of anosmia allegedly received during the Class Period—between 12 and 23 reports out of millions of Zicam units sold by Matrixx—are not material information.

The FDA and the courts have recognized that AERs are not evidence that product use caused the reported event, because they are unreliable and do not consider the background rate in a relevant population of the reported event. They are, however, ubiquitous in the pharmaceutical industry, because the FDA requires companies to file them so the agency can identify potential safety signals justifying further inquiry. The Ninth Circuit's rule would effectively compel pharmaceutical companies to disclose all AERs (to avoid potential securities fraud liability), flooding the market with trivial or meaningless information that would only obscure genuinely important information and thereby undermine sound investment decisionmaking.

B. To plead the element of materiality under § 10(b), a plaintiff alleging that a company failed to disclose AERs should be required to allege facts establishing that the AERs represented statistically significant evidence that the company's product was a cause of the reported event. Statistical significance is a concept very familiar to the law, especially in cases involving alleged product harms, where statistical significance is generally considered essential to proving causation through statistical data. A rea-

sonable investor would rely only on AERs where they provide statistically significant evidence of causation, because only then do AERs provide information that could objectively affect the product's sales. Accordingly, requiring securities-fraud plaintiffs to plead facts establishing that AERs represent statistically significant evidence of causation is entirely consistent with *Basic*'s interpretation of § 10(b)'s materiality requirement. It also ensures that the requirement serves its essential function of filtering out information that is trivial, unreliable, or meaningless.

C. Respondents' complaint fails to plead facts establishing materiality under the foregoing principles. The complaint's own allegations correctly indicate that a leading cause of anosmia is upper respiratory infections associated with the common cold—the very condition for which people take Zicam. Accordingly, to suggest a causal link between Zicam use and anosmia, the reports would have to indicate that the rate of anosmia among Zicam users exceeds, by a statistically significant degree, the rate of anosmia among people with the common cold who do not use Zicam (the "background rate"). The 12 to 23 AERs alleged in the complaint cannot themselves indicate any causal link between Zicam use and anosmia, and the complaint thus fails to allege facts establishing that respondents' omission of the AERs was material.

II. The complaint also does not plead with specificity facts establishing a strong inference of scienter, i.e., that petitioners omitted the AERs with the specific intent to deceive investors. Given that AERs themselves do not establish causation, and

given that the number of reports alleged comes nowhere close to indicating a potentially causal link between Zicam use and anosmia—especially in light of the known association between anosmia and upper respiratory infections—the much more compelling inference is that petitioners did not disclose the AERs because they considered the reports nonmaterial and potentially affirmatively misleading.

ARGUMENT

Respondents' class-action complaint fails to plead facts sufficient to establish the elements of materiality and scienter under § 10(b) of the Securities Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5, 17 C.F.R. § 240.10b-5.

As noted above, the complaint alleges that petitioners failed to disclose the fact that some 12 to 23 Zicam users had reported experiencing anosmia—loss of smell—some time after using the product. J.A. 61a-62a, 68a-69a, 71a-75a, 78a-79a (Compl. ¶¶ 3, 26, 32, 33, 34, 39). That omitted fact allegedly rendered false or misleading statements touting the Zicam-related growth of Matrixx's business and disputing the basis for affirmative declarations that Zicam causes anosmia. *Id.* at 71a-80a (Compl. ¶¶ 32-41); Pet. App. 45a.

The omitted fact—that Matrixx had received 12 to 23 isolated hearsay reports of adverse events following Zicam use, compared to *millions of products sold*—is not material, especially given that the reported adverse event is *already closely associated with the common cold*. Because anecdotal incident reports, under such circumstances, do not provide any scientifically reliable basis for inferring a causal

link between product use and the event, inundating the market with such reports would only confuse and mislead investors by obscuring genuinely material product information. The existence of AERs can provide information material to an investment decision only when the reports reflect statistically significant evidence that product use may cause the reported event. The reports identified in the complaint here fail to show that the rate of anosmia incidents among Zicam users exceeded, by a statistically significant degree, the rate of anosmia among people with the common cold who do not use Zicam. Accordingly, the complaint fails to plead materiality and must be dismissed.

Respondents also do not plead facts establishing a strong inference that petitioners acted with scienter. Because the reports fell so far short of indicating that Zicam use actually causes anosmia, the inference that petitioners intentionally concealed the reports in order to deceive investors is nowhere near as compelling as the obvious alternative explanation: petitioners omitted the reports because they did not believe the reports reflected meaningful evidence of a causal relationship between Zicam use and anosmia, and thus could serve to mislead investors, as well as the product market.

I. ADVERSE EVENT REPORTS THAT DO NOT REVEAL A STATISTICALLY SIGNIFICANT INCREASED RISK OF ADVERSE EVENTS FROM PRODUCT USE ARE NOT MATERIAL INFORMATION

A. A Reasonable Investor Would Not Make Investment Decisions On The Basis Of Isolated Adverse Event Reports

1. *Regulators And Courts Consistently Recognize That Adverse Event Reports Are Not Reliable Indicators Of A Causal Link Between Product Use And The Reported Event*

Various forms of "adverse event reports" ("AERs") are a common feature of the pharmaceutical industry, used to track drug performance by manufacturers, doctors, researchers, and regulators. While AERs are useful for the limited purposes they serve, AERs do *not* reliably indicate even whether an adverse event occurred, much less whether there is a causal link between use of a drug or medical device and a subsequent adverse event.

a. At the most basic level, an AER is any anecdotal report that the user of a drug experienced an adverse event at some point during or following the use of that drug. AERs appear in many forms, including direct complaints by users to manufacturers, reports by doctors about reported or observed patient reactions, more detailed case reports published by doctors in medical journals, or larger scale published clinical studies. *See* FDA, Good Pharmacovigilance, at 4.

AERs are ubiquitous in the pharmaceutical industry, particularly because the FDA has created a

specific system—known as MedWatch—for consumers and healthcare practitioners to report adverse events that follow use of a drug. *See* FDA, Center for Drug Evaluation and Research, Annual Adverse Drug Experience Report: 1996 ("1996 Annual Report") 2 (Oct. 30, 1997).[7] Consumers and healthcare practitioners also may send AERs directly to the manufacturer of a drug, in which case the manufacturer has an obligation to report the adverse event to the FDA. *See* Federal Food, Drug, and Cosmetic Act ("FDCA") § 760, 21 U.S.C. § 379aa; 21 C.F.R. § 314.80.

Reporting of adverse events may be required both for prescription and non-prescription ("over the counter" or "OTC") drugs. Under the current law governing OTC drugs (enacted in 2006, after the close of the Class Period in this case, *see infra* note 9), the details of the reporting obligation depend on whether the drug is marketed based upon an FDA-approved new drug application. *Compare* FDCA § 760, 21 U.S.C. § 379aa (reporting obligations for OTC drugs that do not have new drug application) *with* 21 C.F.R. § 314.80 (reporting obligations for approved new drugs).[8] During the class period there was no requirement that the manufacturer of an

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[7] *Available at* http://druganddevicelaw.net/Annual%20Adverse%20Drug%20Experience%20Report%201996.pdf.

[8] *See* FDCA § 201(p), 21 U.S.C. § 321(p) ("new drug" means "[a]ny drug . . . the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof").

OTC drug, including a homeopathic OTC drug such as Zicam, report adverse events. Current law requires manufacturers of OTC drugs (including homeopathic products) to report any "serious adverse event" within 15 business days, and to keep records of non-serious events for six years (although the latter need not be reported). *See* FDCA §§ 760(c)(1), (e), 21 U.S.C. §§ 379aa(c)(1), (e).[9] Products marketed under a new drug application are subject to more stringent reporting requirements, including filing periodic reports regarding any adverse drug event. *See* 21 C.F.R. § 314.80(c)(2).

b. An AER does not itself show causation—when a consumer takes a drug and thereafter reports an adverse event, the sequence may be mere coincidence. *See* FDA, 1996 Annual Report, at 2. FDA regulations define an "adverse event" as any "adverse event associated with the use of a drug in humans, whether or not considered drug related." 21 C.F.R. § 314.80(a). The FDA's reporting system is designed to be overinclusive, and thus "[c]ausality is not a prerequisite for MEDWATCH reporting." FDA, The Clinical Impact of Adverse Event Reporting ("Adverse Event Reporting") 2 (Oct. 1996).[10] The

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[9] The reporting requirements for OTC drugs in FDCA § 760, 21 U.S.C. § 379aa, were enacted in 2006. *See* Dietary Supplement and Nonprescription Drug Consumer Protection Act ("Act"), Pub. L. No. 109-462, § 2, 120 Stat. 3469, 3469-72 (Dec. 22, 2006); *see also* S. Rep. No. 109-324, at 3 (2006) (Committee report to Dietary Supplement and Nonprescription Drug Consumer Protection Act, Pub. L. No. 109-462) ("Although . . . OTC drugs are not currently required to file adverse event reports, many companies file AERs on a voluntary basis.").

[10] *Available at* http://www.fda.gov/downloads/Safety/MedWatch/UCM168505.pdf.

only requirement is that a person reporting an adverse event must have a "suspicion that a medical product may be related to a serious event." *Id.*

Because the FDA's reporting system is overinclusive, pharmaceutical companies are flooded with hundreds of thousands of adverse event reports every year, regardless whether there is any evidence of a causal link between any of the reported events and their drugs. For example, in 2009, the FDA received more than half a million adverse event reports for drugs and therapeutic biologic products. *See* FDA, Adverse Event Reporting System (AERS), Reports Received and Reports Entered into AERS by Year (Mar. 31, 2010) ("FDA AERS Reports Received").[11] In the first quarter of 2010 alone, the FDA received more than 150,000 AERs. *Id.*

c. It is widely recognized that these ubiquitous AERs are inherently unreliable and do not by themselves establish *even that an adverse event actually occurred*, much less that there was a causal link between a reported event and a drug. *See, e.g.*, S. Rep. No. 109-324, at 6 ("The fact of a report of an adverse event is not determinative that the event occurred or that the event was caused by a consumer's use of the product."); 21 C.F.R. § 314.80(k) (reporting of adverse event by manufacturer is not admission of causality).

i. To start, the FDA emphasizes that MedWatch AERs may be unreliable and do not themselves prove that a drug causes an adverse event. AERs

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[11] *Available at* http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformaion/Surveillance/AdverseDrugEffects/ucm070434.htm.

"are subject to a variety of reporting biases," the FDA has explained, in that "some observations could reflect concomitant treatment, not the product itself, and other factors, including the disease being treated, other comorbidities or unrecorded confounders, may cause the events to be reported." FDA, Good Pharmacovigilance, at 9. The agency division that monitors AERs further explains that "any given" AER is of limited utility, because "there is no certainty that the suspected drug caused" the reported event. FDA, 1996 Annual Report, at 2.

The probative value of an AER is especially weak when the "adverse event may have been related to an underlying disease for which the drug was given." *Id.* In that situation—which involves what statisticians call a "confounding indicator"—the lay consumer will often associate the adverse event with use of the drug, rather than with the underlying condition that actually caused it. *See* FDA, Good Pharmacovigilance, at 7, 9; FDA, 1996 Annual Report, at 2. There is also the ever-present random chance: although the consumer may associate the event with the drug, in fact the event "may have occurred by chance at the same time as the suspect drug was administered." FDA, 1996 Annual Report, at 2.

Because the FDA recognizes that AERs are "quite subjective and imprecise," the agency explains that they cannot be used by themselves to calculate the "incidence rate" of an adverse event—i.e., how often the event actually occurs following use of a product. *See* FDA, Adverse Event Reporting, at 5. AERs thus may not indicate any association greater than the "background" incidence rate—i.e., how of-

ten the event occurs in the general population or in a relevant sub-population: "[I]t is well known that placebos and even no treatment can be associated with adverse events." *Id.* (footnotes omitted). This is true, the FDA explains, even in the case of accumulated AERs. *See* FDA, 1996 Annual Report, at 2; *see also* Requirements on Content and Format of Labeling for Human Prescription Drugs and Biological Prods., 71 Fed. Reg. 3922, 3950 (Jan. 24, 2006) ("[f]or postmarketing reporting the impetus for reporting, the frequency with which a suspected adverse reaction is reported, and the number of exposures to the drug compared to the number of suspected reactions reported are unknown"); FDA, Guidance for Industry: ICH E2E Pharmacovigilance Planning 11 (Apr. 2005) (warning that data accompanying adverse event reports is often incomplete).[12] At most, AERs can be used to calculate "crude adverse event reporting rates as a valuable step" in investigating adverse events and forming hypothesis, but such rates "can by no means be considered incidence rates, for either absolute or comparative purposes." FDA, Good Pharmacovigilance, at 11.

The "great utility" of AERs thus is not that they establish an association between a drug and an adverse event, but rather that they may "generate signals of potential problems that warrant further investigation." Adverse Event Reporting at 6; *see also* S. Rep. No. 109-324, at 7 (AER reporting systems "are designed to generate signals which require further evaluation"); FDA, Good Pharmacovigilance, at

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[12] *Available at* http://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm129423.pdf.

4. When the FDA identifies such "signals," it follows up with further research, including commissioning studies to determine whether there may, in fact, be an association between a drug and a reported adverse event. *See* FDA, Adverse Event Reporting, at 6-7; *see also Stephens' Detection of New Adverse Drug Reactions* 354-59 (John Talbot & Patrick Walker eds., 5th ed. 2004). The FDA does not apply any particular metric for determining when a sufficient "signal" exists to justify further inquiry; instead, whether the FDA will exercise its discretion turns upon its subjective and fact-specific estimation of the signal strength established by AERs in any particular case. *See* Adverse Event Reporting at 7; *id.* at 5 (because "recognition of [adverse events] . . . is quite subjective and imprecise," agency must engage in "careful, thoughtful review of adverse event reports").[13]

ii. Courts, too, have recognized that because AERs in any of their various forms are, at bottom, nothing more than uncontrolled and anecdotal hearsay information, they are far too unreliable to establish causation. Courts thus generally exclude expert testimony on medical causation when that testimony is premised solely upon AERs. A representative

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[13] Although the agency assumes that due to underreporting AERs "generally represent only a small portion of the number" of adverse events in a population, *see* FDA, Adverse Event Reporting, at 5, it recognizes that calculating reporting rates based upon AERs is usually a precursor to determining whether a safety signal indicates a potential safety risk, *see* FDA, Good Pharmacovigilance, at 17. Only in rare cases, such as when "coincidental drug-event associations are [highly] unlikely," will a handful of AERs themselves justify further study. *See* FDA, Adverse Event Reporting, at 7.

sample of 50 federal and state opinions holding that (1) AERs and similar reports or (2) expert testimony premised upon them are unreliable and inadmissible is available at Appendix A. As these opinions discuss, AERs suffer from two particular infirmities that make them particularly unreliable indicators of causation.

First, consumer complaints and AERs are hearsay, and, in cases involving multiple layers of reporting, may be double or treble hearsay. Such "second-or-third hand reports . . . have inherent biases" that make them "unreliable for determining causation." *DeLuca v. Merrell Dow Pharms., Inc.*, 791 F. Supp. 1042, 1050, 1057 (D.N.J. 1992), *aff'd* 6 F.3d 778 (3d Cir. 1993); *accord Richardson v. Richardson-Merrell, Inc.*, 649 F. Supp. 799, 801 n.5 (D.D.C. 1986) (AERs are not "exceptions to the hearsay rule"), *aff'd on other grounds* 857 F.2d 823 (D.C. Cir. 1988); *Wolf v. Proctor & Gamble Co.*, 555 F. Supp. 613, 620 (D.N.J. 1982) (consumer complaint to company is hearsay); *Smith v. Pfizer Inc.*, 2010 WL 1754443, at *5 (M.D. Tenn. Apr. 30, 2010) (isolated AERs are "second- or third-hand reports" and not admissible to show causation or notice); *Peters v. Johnson & Johnson Prods., Inc.*, 783 S.W.2d 442, 444-45 (Mo. Ct. App. 1990) (consumer complaints do not fall under business exception to hearsay rule). An AER is not produced by a government agency and thus has no entitlement to the presumption of trustworthiness accorded to public records under an exception to the hearsay rule. *See* Fed. R. Evid. 803(8); *see also Appleby v. Glaxo Wellcome, Inc.*, 2005 WL 3440440, at *3 (D.N.J. Dec. 13, 2005).

Second, even assuming they are trustworthy reports of the basic incident, AERs do not reliably indicate causation because they "simply describe[] reported phenomena *without comparison to the rate at which the phenomena occur in the general population or in a defined control group*." *Casey v. Ohio Med. Prods.*, 877 F. Supp. 1380, 1385 (N.D. Cal. 1995) (emphases added). AERs also "do not isolate and exclude potentially alternative causes; and do not investigate or explain the mechanism of causation." *Id.*; *see also Siharath v. Sandoz Pharms. Corp.*, 131 F. Supp. 2d 1347, 1359-63 (N.D. Ga. 2001) (collecting cases on use of AERs and holding that "even if relevant case reports existed, they cannot establish general causation"). Instead, AERs may reflect nothing more than a chance sequence of events, i.e., a person takes a drug and thereafter experiences an adverse event. *See, e.g.*, *Wade-Greaux v. Whitehall Labs., Inc.*, 874 F. Supp. 1441, 1481 (D.V.I. 1994) (drug experience reports and product liability lawsuits "represent anecdotal information of chance associations"); *Saari v. Merck & Co.*, 961 F. Supp. 387, 394 (N.D.N.Y. 1997) (AER is "simply a report of what plaintiff told [her doctor] about what she believed was her reaction to the [drug]"). But as the familiar Latin logical fallacy *post hoc ergo propter hoc* admonishes, mere temporal association between two events does not suffice to show a causal relationship between the two. *See McLain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1243 (11th Cir. 2005).

2. *Anecdotal Hearsay AERs Themselves Are Not Material And Requiring Their Disclosure Would Affirmatively Harm The Markets*

In light of their well-recognized limitations, the mere existence of AERs is not information a reasonable investor would consider material to her investment decision. Indeed, treating them as material would effectively compel companies to disclose all such reports, inundating the market with useless, trivial, and even affirmatively misleading information, which will only undermine reasoned investment decisionmaking.

a. As noted above, a fact is not material unless there is "a substantial likelihood" that a reasonable investor would view it as "significantly alter[ing] the total mix of information made available." *Basic*, 485 U.S. at 232 (internal quotation marks omitted). Information that does not shed significant light on the value of an issuer's product cannot be "significant to the reasonable investor's trading decision." *Id.* at 235.

Information that reliably indicates a drug may cause an adverse health effect can be potentially material, because a manufacturer of a drug that harms consumers may lose market share, face regulatory action, or be subject to costly litigation. But absent a reliable indication of a causal link to an adverse health effect, any of those potential consequences for the manufacturer's business would be wholly speculative, and a reasonable investor would not base an investment decision on unreliable speculation. *See In re Rockefeller Ctr. Props., Inc. Sec. Litig.*, 184 F.3d 280, 290 (3d Cir. 1999) ("In determining the effect of

an omission, we examine whether the information omitted is speculative or unreliable, or if it is contingent." (internal citation omitted)); *see also Epstein v. Wash. Energy Co.*, 83 F.3d 1136, 1141 (9th Cir. 1996); *Craftmatic Sec. Litig. v. Kraftsow*, 890 F.2d 628, 645-46 (3d Cir. 1989); *In re Par Pharm., Inc. Sec. Litig.*, 733 F. Supp. 668, 678 (S.D.N.Y. 1990). AERs do not provide the reliable basis for inferring a causal association on which a reasonable investor would rely.

AERs are also immaterial because they merely indicate what a reasonable investor *already knows*: from time to time consumers experience adverse events after using a company's drug. *See In re Carter-Wallace, Inc. Sec. Litig.*, 220 F.3d at 41 ("Some adverse events may be expected to occur randomly, especially with a drug designed to treat people that are already ill."); *cf. Jackvony v. RIHT Fin. Corp.*, 873 F.2d 411, 415 (1st Cir. 1989) (Breyer, J.) (internal merger discussions categorically nonmaterial because "[a]ny reasonably sophisticated investor in securities buying shares in a large corporation would expect that, from time to time, other corporations might express an interest in buying, or that the large corporation's directors might discuss what it should do if it obtains such offers"). Given the presumed efficiency of securities markets, *see Basic*, 485 U.S. at 247, the reasonable investor will be fully aware that the FDA receives hundreds of thousands of AERs every year, *see supra* at 19-20, and that neither the FDA nor courts treat those AERs as reliable indicators of a causal association between use of the drug and the reported adverse event, *see supra* at 20-25.

b. Disclosure of AERs not only would be unnecessary for a hypothetical reasonable investor, it would be affirmatively harmful to actual investors and the market generally.

Under the rule adopted by the Ninth Circuit, companies will be driven to disclose essentially *all* AERs in order to inoculate themselves against the securities-fraud suits that would otherwise inevitably follow any regulatory warning letter or voluntary recall. Such actions are hardly an unusual feature of the pharmaceutical business (or indeed any product manufacturing business generally). *See* FDA, The Enforcement Story 10-9, 10-15 (2009) (FDA's Center for Drug Evaluation and Research, which regulates OTC and prescription drugs, issued 379 product recalls and 87 warning letters in the fiscal year 2008).[14] When warning letters are issued—or, similarly, when a product is voluntarily recalled—the price of the company's stock often drops, which in turn prompts securities class-action lawyers to file § 10(b) actions asserting that if the company had disclosed whatever safety or performance indicators it had before the regulatory action or recall, investors would have sold their shares and avoided the stock-price loss. *See N.J. Carpenters Pension & Annuity Funds v. Biogen IDEC Inc.*, 537 F.3d 35, 47 (1st Cir. 2008) (situation is "paradigmatic of securities fraud cases against drug development companies"). And of course the strike value of such class action suits can "impose substantial costs" even "on companies and individuals whose conduct conforms

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[14] *Available at* http://www.fda.gov/downloads/ICECI/EnforcementActions/EnforcementStory/UCM129824.pdf.

to the law." *Tellabs*, 551 U.S. at 313; *see Merrill Lynch, Pierce, Fenner & Smith Inc. v. Dabit*, 547 U.S. 71, 80 (2006) ("Even weak cases brought under [Rule 10b-5] may have substantial settlement value . . . because '[t]he very pendency of the lawsuit may frustrate or delay normal business activity.'" (quoting *Blue Chip Stamps v. Manor Drug Stores*, 421 U.S. 723, 740 (1975)).

Accordingly, if the law subjects companies to the costs of securities-fraud lawsuits for failing to disclose AERs as unreliable as those at issue here, companies would have a strong incentive simply to disclose all the AERs they receive. But to avoid confusion about the actual value of the information being disclosed, companies might also include with the disclosure the additional statements that AERs are uncontrolled, unconfirmed multi-layer hearsay, which do not themselves demonstrate any incidence beyond known background incidence, and which the FDA and courts reject as the basis for establishing a causal inference. Such disclaimer language would be an entirely accurate characterization of AERs, but it would of course also make disclosure of the AERs utterly unhelpful to investors—which simply demonstrates why *AERs themselves*, when accurately described and understood, do not provide investors with material information.

Whether or not companies provide investors additional information necessary to understand the function and value of AERs, they will certainly have an incentive to disclose the AERs themselves, as noted. This will undermine reasoned investment decisionmaking in at least two ways. First, actual investors would have no meaningful basis for under-

standing whether and when product safety concerns are "real," as opposed to merely the predictable and common noise of untested AERs. Investors generally are not scientists or epidemiologists and cannot be expected to sift significant from insignificant scientific data with ease. And they presumably expect companies in general to disclose only meaningful adverse information, and so seeing the disclosure of AERs could lead some or many investors to believe, erroneously, that the AERs actually reflect a serious product concern. In other words, disclosure of AERs can mislead investors into undervaluing or prematurely selling a security, which is as just as economically harmful to investors and the markets as overvaluing a security or holding it too long.

Second, in addition to misleading investors by drawing their attention to unreliable information, a materiality rule that leads companies to disclose AERs as a matter of course to avoid securities-fraud liability will also obscure information that is genuinely material. As discussed above, this Court has long recognized that the "role of the materiality requirement" is to "filter out" information such as AERs because, although a reasonable investor "would not consider [such information] significant," *Basic*, 485 U.S. at 234, disclosure of the information would bury investors in an "avalanche of trivial information," *TSC Indus.*, 426 U.S. at 448.

Excessive disclosure makes "informed decisionmaking" more difficult, *id.* at 448-49, and thereby harms markets just as assuredly as does insufficient disclosure. "Studies have shown that as a decision maker is given more information, decision quality initially increases; once the information level

reaches a certain point, however, the decision maker's decision quality decreases if she is given additional information." Troy A. Paredes, *Blinded By The Light: Information Overload and its Consequences for Securities Regulation*, 81 Wash. U. L.Q. 417, 441 (2003). In fact, the effect of *over*disclosure is essentially the same as *non*disclosure, because genuinely material information becomes hidden in plain sight. "[T]he more information there is the more each bit of it is diluted. The immediate and salient crowds out the less attention-grabbing." Donald C. Langevoort, *Toward More Effective Risk Disclosure for Technology-Enhanced Investing*, 75 Wash. U. L.Q. 753, 759 (1997) (footnote omitted). As a result of this "information overload," a "large amount of information" can become "equivalent to no information at all." Cass R. Sunstein, *Informing America: Risk, Disclosure, and the First Amendment*, 20 Fla. St. U. L. Rev. 653, 668 (1993).

The problem of overdisclosure is well recognized in the law and literature concerning product manufacturers' duty to warn consumers about product risks. *See, e.g.*, *Robinson v. McNeil Consumer Healthcare*, 2010 WL 3156548, at *7 (7th Cir. Aug. 11, 2010) ("information overload would make label warnings worthless to consumers"); *Cotton v. Buckeye Gas Prods. Co.*, 840 F.2d 935, 937-38 (D.C. Cir. 1998) ("The inclusion of each extra [warning] item dilutes the punch of every other item. Given short attention spans, items crowd each other out; they get lost in fine print."); W. Kip Viscusi, *Individual Rationality, Hazard Warnings, and the Foundations of Tort Law*, 48 Rutgers L. Rev. 625, 633 (1996) ("consumers may be inundated with so many pieces of in-

formation that they cannot process all the warning messages they receive"). The FDA, in particular, has opined that "labeling that includes theoretical hazards not well-grounded in scientific evidence can cause meaningful risk information to 'lose its significance.'" 71 Fed. Reg. at 3935. "Overwarning, just like underwarning, can similarly have a negative effect on patient safety and public health." *Id.* The same problem exists for overdisclosure in securities filing, as this Court has recognized. *See TSC Indus.*, 426 U.S. at 448-49.

The "filtering" effect of § 10(b)'s materiality requirement, in short, is just as important as the underlying disclosure principle it constrains. Section 10(b) should not be construed and applied in a way that will cause companies to overload investors with trivial, unreliable product information. AERs can be material only when they reflect a scientifically reliable basis for inferring a potential causal link between product use and the adverse event, as the next section shows.

B. Statistical Significance Should Be Required As A Threshold Element Of Materiality In § 10(b) Cases Based On Undisclosed AERs

Statistical significance is a concept very familiar to the law. In legal contexts where it is necessary to distinguish random chance from a causal relationship, courts regularly use statistical significance to draw that distinction. And causation is ultimately what matters here: the existence of facts indicating a causal link between use of a significant company product and an adverse health event could be impor-

tant to a reasonable investor, whereas routine, unreliable reporting "noise" would not be, as shown above. Accordingly, before disclosure of AERs is required under the securities laws, they at least must "provide statistically significant evidence that the ill effects may be caused by—rather than randomly associated with—use of the drug[]." *Oran v. Stafford*, 226 F.3d 275, 284 (3d Cir. 2000) (Alito, J.) (internal quotation marks omitted); *see Masters v. GlaxoSmithKline*, 271 F. App'x 46, 50 (2d Cir. 2008); *In re Carter-Wallace, Inc. Sec. Litig. (Carter-Wallace I)*, 150 F.3d 153, 157 (2d Cir. 1998).[15] This means that § 10(b) plaintiffs must at least plead facts establishing that the rate of reported adverse incidents among product users exceeded the relevant background rate by a statistically significant degree.

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[15] Even then, AERs are not *necessarily* material—the underlying data may be flawed, the indicated association may not be causal, and even with a causal link, the link may be too weak or the effect too minor (or both) to have consequences for product sales and company finances. *See, e.g.*, *Masters*, 271 F. App'x at 50 ("reports of harmful drug effects are immaterial—and thus need not be disclosed—unless those reports (1) show statistically significant evidence of an adverse effect; (2) establish that the adverse effect threatens the 'commercial viability' of the drug; and (3) show that the effect poses a significant risk to the company's future earnings" (quotation omitted)). The issue here is whether statistical significance is a *necessary*—though perhaps not always sufficient—threshold requirement for pleading and proving materiality.

1. *Statistical Significance Is A Commonly Recognized And Understood Means For Distinguishing Between Chance And Association*

Statistical significance is a device for analyzing the relationship between two events—a device almost as familiar to courts as it is to scientists.

a. Scientists commonly measure whether data indicates an association between use of a product and an event by determining whether the data is statistically significant. Green et al., Reference Guide on Epidemiology, at 354-58. An "association" between two variables—for example, a drug and a health event—exists when the variables "occur together more frequently than one would expect by chance." *Id.* at 348.

Textbooks, treatises, and articles have been written on statistical analysis and the concept of statistical significance. What follows is necessarily a capsule summary, for purposes of explaining the importance of statistical significance in this context.

A researcher examining the potential association between two events begins with a "null hypothesis," i.e., there is *no* association in fact, and any association observed in a sample will be "due to the luck of the draw." David H. Kaye & David A. Freeman, Reference Guide on Statistics, *in* Federal Judicial Center, Reference Manual on Scientific Evidence ("Reference Guide on Statistics") 122 (2d ed. 2000). The researcher then determines whether to reject the null hypothesis based upon the observed data. The researcher calculates a "p-value," which is the probability that, if there was no actual association between the variables, an association in any given

sample would be observed simply as a result of random error. The researcher then compares that value against a "significance level" selected during research design. If the p-value is lower than the significance level, then the researcher can be confident that random error is *not* responsible for the observed association, and the null hypothesis is rejected. *Id.* at 124.[16]

Generally statisticians and epidemiologists use a .05 significance level, meaning there is only a 5% probability of observing an association when there is actually no association. Green et al., Reference Guide on Epidemiology, at 358. This Court has recognized and employed this standard, explaining in both the jury discrimination and employment law contexts that the null hypothesis may be rejected after taking a "large sample[]" and observing an association more than "two or three standard deviations" from the "expected value" indicated by the null hypothesis.[17] *Castaneda v. Partida*, 430 U.S. 482, 496 n.17 (1977); *see Hazelwood Sch. Dist. v. United States*, 433 U.S. 299, 311 n.17 (1977). Although statisticians and courts debate the "finer points," including whether there are situations in which a lower or

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[16] Statistical significance does not reveal whether there is a "practically important" link between the two variables observed. Kaye & Freeman, Reference Guide on Statistics, at 124. In other words, the association may be very weak—for example, in the product realm, indicating only a slight increase in risk from use of the product.

[17] Two or three standard deviations from the expected value indicated by the null hypothesis corresponds to .05 and .01 significance levels. Kaye & Freeman, Reference Guide on Statistics, at 124 n.138.

higher significance level than .05 is appropriate, significance testing at some meaningful level is a generally accepted means of determining whether an observed association may be the basis for further reasoning regarding causation. *See Mister v. Ill. Cent. Gulf R.R. Co.*, 832 F.2d 1427, 1430-31 (7th Cir. 1987); Daniel L. Rubinfeld, *Econometrics in the Courtroom*, 85 Colum. L. Rev. 1048, 1054 (1985) ("The importance of determining meaningful statistical significance levels is a concern which permeates nearly every context in which statistical methods are introduced in litigation.").[18]

b. Courts employ statistical significance devices in a wide variety of legal contexts to distinguish between random occurrence and associations that

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[18] Various analytical methods can be used to determine whether data reflect a statistically significant result. One such method, calculating confidence intervals, is especially useful for epidemiological analysis of drug safety, because it allows the researcher to estimate the *relative risk* associated with taking a drug by comparing the incidence rate of an adverse event among a sample of persons who took a drug with the background incidence rate among those who did not. Dividing the former figure by the latter produces a relative risk figure (e.g., a relative risk of 2.0 indicates a 50% greater risk among the exposed population). The researcher then calculates the confidence interval surrounding the observed risk, based on the preset confidence level, to reflect the degree of certainty that the "true" risk falls within the calculated interval. If the lower end of the interval dips below 1.0—the point at which the observed risk of an adverse event matches the background incidence rate—then the result is not statistically significant, because it is equally probable that the actual rate of adverse events following product use is identical to (or even less than) the background incidence rate. Green et al., Reference Guide on Epidemiology, at 360-61. For further discussion, *see id.* at 348-61.

could be causal. Such contexts include product liability, toxic torts, employment discrimination, equal protection jury discrimination claims, and vote dilution claims.

Product liability is the context most pertinent to this case, which involves statements and omissions affecting the commercial viability of a pharmaceutical product based on potential safety concerns. The issue in product liability cases based on epidemiological evidence of potential harm is very similar to the question facing reasonable investors who learn of an isolated AER, *viz.*, whether the available information indicates a causal link between the product and an adverse health event. Nearly identical causation-related issues are raised in toxic tort litigation as well. And it is well-settled in the product liability and toxic tort contexts that the simple numerical reporting of anecdotal observations or raw numbers of adverse events will *not* suffice to establish causation, or even to support an admissible expert opinion on causation.

This Court has upheld the exclusion of expert testimony on causation[19] premised upon epidemiol-

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[19] Product liability suits require proof of both general and specific causation. *See generally* Restatement (Second) of Torts § 430 (1965) (causation necessary for tort liability); Green et al., Reference Guide on Epidemiology, at 392, 396 (distinguish general from specific causation). *General* causation refers to whether a given drug is generally capable of causing a particular adverse event. *See, e.g., McLain*, 401 F.3d at 1239. *Specific* causation is whether the drug caused that adverse event in plaintiff's specific case. *See, e.g., Baker v. Chevron USA, Inc.*, 680 F. Supp. 2d 865, 874 (S.D. Ohio 2010). Statistical significance is mainly relevant to proof of general causation.

ogical data that is not statistically significant. *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 145 (1997). Statistical significance, the Court recognized, is a means by which an expert's opinion evidence is "connected to existing data," as opposed to being a mere "*ipse dixit*" opinion. *Id.* at 146. And lower courts consistently reject as unreliable expert opinion regarding causation when it relies upon epidemiological or other numerical data regarding incidence rates that is not statistically significant. *See, e.g., Hendrix v. Evenflo Co.*, 609 F.3d 1183, 1196-97 (11th Cir. 2010); *Wells v. SmithKline Beecham Corp.*, 601 F.3d 375, 380 (5th Cir. 2010); *Hollander v. Sandoz Pharms. Corp.*, 289 F.3d 1193, 1215-16 (10th Cir. 2002); *Glastetter v. Novartis Pharm. Corp.*, 252 F.3d 986, 990 (8th Cir. 2001); *Brock v. Merrell Dow Pharms., Inc.*, 884 F.2d 166, 167 (5th Cir. 1989); *Baker v. Chevron USA, Inc.*, 680 F. Supp. 2d 865, 881-82 & nn.11-12 (S.D. Ohio 2010); *Milward v. Acuity Speciality Prods. Grp., Inc.*, 664 F. Supp. 2d 137, 149 (D. Mass. 2009); *Cano v. Everest Minerals Corp.*, 362 F. Supp. 2d 814, 821 (W.D. Tex. 2005); *Newman v. Motorola, Inc.*, 218 F. Supp. 2d 769, 775-79 (D. Md. 2002), *aff'd* 78 F. App'x 292 (4th Cir. 2003); *In re Norplant Contraceptive Prods. Liab. Litig.*, 215 F. Supp. 2d 795, 831 (E.D. Tex. 2002); *Chambers v. Exxon Corp.*, 81 F. Supp. 2d 661, 665 (M.D. La. 2000); *Marder v. G.D. Searle & Co.*, 630 F. Supp. 1087, 1092 (D. Md. 1986), *aff'd sub nom., Wheelahan v. G.D. Searle & Co.*, 814 F.2d 655 (4th Cir. 1987); *Merrell Dow Pharms., Inc. v. Havner*, 953 S.W.2d 706, 723-24 (Tex. 1997).

In excluding this evidence, courts recognize that without statistical significance, "'there is simply

too great an analytical gap between the data and the opinion proffered.'" *Baker*, 680 F. Supp. 2d at 881-82 (quoting *Joiner*, 522 U.S. at 146)). By "scrutinizing the basis, reasoning, and statistical significance of studies presented" by the parties, courts ensure that lay jurors are not misled by raw numbers that may seem compelling in the abstract, but do not, in fact, reliably indicate the possibility of a causal link between the drug and an adverse event. *Brock*, 884 F.2d at 167.[20]

Courts also use statistical significance to distinguish between chance and association in employment discrimination cases. This Court invoked statistical significance in *Hazelwood* to explain how an employer could rebut a prima facie case of pattern-or-practice discrimination, *see* 433 U.S. at 311 & n.17, and again in *Bazemore v. Friday*, 478 U.S. 385 (1986), in noting that regression analyses offered to prove discrimination did indicate "statistically significant[] racial effect[s]," *id.* at 399-401 & n.9. Lower courts have similarly emphasized that numerical data on employment actions (hiring, promotion, firing, etc.) "will not permit an inference of discrimination" in a pattern-or-practice case unless the data reveal a "statistical[ly] significan[t]" correlation between the employment action and the prohibited classification. *Segar v. Smith*, 738 F.2d 1249, 1283

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[20] Even data that is statistically significant may not be reliable, if the data source itself is not sufficiently reliable. In *Wells*, for example, the Fifth Circuit explained that a poster presentation that was never peer-reviewed or published would not be sufficiently reliable to serve as a basis for an expert opinion on causation, even though the presentation described statistically significant findings. 601 F.3d at 380.

(D.C. Cir. 1984); *see Kohlbek v. City of Omaha*, 447 F.3d 552, 557 (8th Cir. 2006); *Schwartz v. Veneman*, 252 F.3d 436, 2001 WL 361113, at *1 (5th Cir. 2001); *Anderson v. Zubieta*, 180 F.3d 329, 339-40 (D.C. Cir. 1999); *Anderson v. Douglas & Lomason Co.*, 26 F.3d 1277, 1291 n.26 (5th Cir. 1994); *Ottaviani v. State Univ. of N.Y.*, 875 F.2d 365, 371 (2d Cir. 1989); *Palmer v. Shultz*, 815 F.2d 84, 96 (D.C. Cir. 1987); *Mister*, 832 F.2d at 1431; *Lilly v. Harris-Teeter Supermarket*, 720 F.2d 326, 337-38 (4th Cir. 1983); *Taylor v. Teletype Corp.*, 648 F.2d 1129, 1133 (8th Cir. 1981). The same is generally true for disparate impact cases: given the "dangers of relying on . . . raw, undifferentiated data," *Soria v. Ozinga Bros., Inc.*, 704 F.2d 990, 996 (7th Cir. 1983), a plaintiff seeking to establish a prima facie case based on numerical data must show a "statistically significant adverse effect of a rule that is neutral in its terms," *Wis. Cmty. Servs., Inc. v. City of Milwaukee*, 465 F.3d 737, 756 (7th Cir. 2006) (Easterbrook, J., concurring); *see McClain v. Lufkin Indus.*, 519 F.3d 264, 280 (5th Cir. 2008); *Paige v. California*, 233 F. App'x 646, 648 (9th Cir. 2007) (collecting cases); *Cooper v. S. Co.*, 390 F.3d 695, 716 (11th Cir. 2004); *Malave v. Potter*, 320 F.3d 321, 327 (2d Cir. 2003); *Anderson*, 180 F.3d at 340; *Hameed v. Int'l Ass'n of Bridge, Structural & Ornamental Iron Workers*, 637 F.2d 506, 512-14 (8th Cir. 1980).[21]

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[21] Some courts have followed the Equal Employment Opportunity Commission's ("EEOC") "four-fifths rule," under which a prima facie case of disparate impact may be established by a showing that the minority pass rate under an employment test is less than four-fifths (80%) of the majority pass rate. *See Smith v. Xerox Corp.*, 196 F.3d 358 (2d Cir. 1999).

Courts also use statistical significance testing to assess whether chance or discrimination explains racial disparities in the selection of juries in violation of the Equal Protection Clause. In *Castaneda*, the Court explained the "general rule" that for "large samples, if the difference between the expected value and the observed number is greater than two or three standard deviations, then the hypothesis that the jury drawing was random" rather than racially motivated "would be suspect to a social scientist." 430 U.S. at 496 n.17. Lower courts have likewise recognized that "comparing straight racial percentages is of little value," *Jefferson v. Morgan*, 962 F.2d 1185, 1189 (6th Cir. 1992), and thus have modeled standard deviations and calculated statistical significance to "determine if chance alone could account for a meager representation of minorities" on jury arrays, *Alston v. Manson*, 791 F.2d 255, 258 (2d Cir. 1986); *see Moultrie v. Martin*, 690 F.2d 1078, 1082 (4th Cir. 1982).

Statistical significance analysis is also relevant in establishing claims under § 2 of the Voting Rights Act. In *Thornburg v. Gingles*, 478 U.S. 30 (1986), this Court approved the district court's threshold "three-part inquiry" into the voting data: "[D]id the data reveal any correlation between the race of the voter and the selection of certain candidates; was the revealed correlation statistically significant; and was

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But even the EEOC acknowledges that the four-fifths rule should be supplemented with a statistical significance test in some cases, *see* 29 C.F.R. § 1607.4(D), and, in any event, the four-fifths rule "has . . . been used with caution" and "has been criticized as unreliable and overly simplistic," *Frazier v. Consol. Rail Corp.*, 851 F.2d 1447, 1451 (D.C. Cir. 1988).

the difference in black and white voting patterns 'substantively significant'?" *Id.* at 53, 58, 61. Courts subsequently have examined whether vote dilution plaintiffs relying upon statistical data have made a statistically significant threshold showing of political cohesiveness and racial bloc voting, and have rejected expert opinions that fail to include such analysis. *See Monroe v. City of Woodville*, 881 F.2d 1327, 1330-32 (5th Cir. 1989); *Overton v. City of Austin*, 871 F.2d 529, 544-45 (5th Cir. 1989) (Jones, J., concurring); *cf. Sanchez v. Colorado*, 97 F.3d 1303, 1317 (10th Cir. 1996) (discussing proof of "statistically significant polarization"). Statistical significance testing can also "cast considerable doubt on the existence of a causal link" in other types of claims of discriminatory effect in violation of § 2. *See Irby v. Va. State Bd. of Elections*, 889 F.2d 1352, 1358-59 (4th Cir. 1989) (affirming dismissal of claim that appointment system for local school boards has discriminatory effect and "recogniz[ing] the dangers of drawing conclusions from statistics involving boards with relatively few members").

2. *A § 10(b) Case Based On Nondisclosure Of AERs Must Plead Facts Showing A Statistically Significant Correlation Between Product Use And The Reported Event*

Drawing upon the many other legal contexts where statistically significant evidence is required, § 10(b) cases based on a company's failure to disclose AERs involving a company product should fail at the threshold when the complaint does not plead facts establishing that the AERs reflect a statistically significant correlation between use of the product and the reported adverse event. When the complaint

merely cites AERs without a statistically meaningful comparison to relevant background incident rates, it does nothing to show that the AERs reflect a potentially causal relationship between product use and the reported event and thus could affect a reasonable investor's decisionmaking. *See Oran*, 226 F.3d at 284; *Masters*, 271 F. App'x at 50; *Carter-Wallace I*, 150 F.3d at 157.

Requiring that AERs be statistically significant in order to sufficiently allege materiality fully accord with, and indeed implements, this Court's ruling in *Basic*. As explained above, the Court in *Basic* held that a fact is material for purposes of securities fraud where there is "'a substantial likelihood'" that its disclosure "'would have been viewed by the reasonable investor as having significantly altered the "total mix" of information made available.'" 485 U.S. at 231-32 (quoting *TSC Indus.*, 426 U.S. at 449). The Court applied that principle to reject a proposed bright-line rule that would exempt disclosure of all pre-merger negotiations "not yet at the agreement-in-principle stage." *Id.* at 233-36. As the Court explained, the proposed rule would "artificially exclud[e] from the definition of materiality information . . . which would otherwise be considered significant to the trading decision of a reasonable investor." *Id.* at 236. Here, in contrast, far from "artificially excluding" otherwise relevant information, the statistical significance standard *defines* the information a reasonable investor would consider relevant, i.e., information that may indicate that the company product can cause an adverse event, thereby potentially exposing the company to financial losses. And it works to "filter out essentially useless information,"

namely, AERs reporting events that cannot be distinguished from background incident rates of that event. *Id.* at 234. Filtering out this type of information is precisely "[t]he role of the materiality requirement." *Id.*

Statistical significance also gives both companies *and* investors guidance they need to understand corporate disclosure obligations. As discussed above, absent any intelligible basis for determining when AERs become material, companies will have strong incentives to disclose *all* AERs, which will deprive investors of any sound basis for understanding which AER disclosures actually matter. This Court's admonition bears repeating: a materiality rule that causes a company "simply to bury the shareholder in an avalanche of trivial information," is hardly a rule that would be "conducive to informed decisionmaking." *TSC, Indus.*, 426 U.S. at 448-49; *see supra* at 30-32. Statistical significance is a perfectly intelligible basis for distinguishing material from immaterial AERs, thereby avoiding an avalanche of overdisclosure, while still permitting plaintiffs to proceed when a company fails to disclose AERs that actually could matter to a reasonable investor, i.e., AERs that reveal a potentially causal link between a significant company product and harm to product users.[22]

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[22] In some drug product liability cases—especially those involving rare or "novel" events—courts permit an inference of causation on the basis of scientifically reliable evidence other than statistically significant epidemiological data. *See, e.g., Ealy v. Richardson-Merrell, Inc.*, 897 F.2d 1159, 1162-64 (D.C. Cir. 1990) (discussing cases); *In re Neurontin Mktg., Sales Practices & Prods. Liability Litig.*, 612 F. Supp. 2d 116, 141 (D. Mass. 2009). In such cases experts rely on a lengthy list of fac-

C. Respondents' Complaint Does Not Allege Facts Establishing That The AERs At Issue Revealed An Incidence Rate That Differed From The Relevant Background Rate By Any Statistically Significant Degree

According to respondents, the complaint satisfies any statistical significance "benchmark" for materiality because it "tabulates at least 23 specifically linked Zicam-anosmia complaints." Opp. to Pet. for Cert. 20. Respondents' submission only illustrates

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tors to draw reliable inferences, including, for example, (1) the "strength" of the association, including "whether it is statistically significant"; (2) temporal relationship between exposure and the adverse event; (3) consistency across multiple studies; (4) "biological plausibility"; (5) "consideration of alternative explanations" (i.e., confounding); (6) "specificity" (i.e., whether the *specific* chemical is associated with the *specific* disease at issue); and (7) dose-response relationship (i.e., whether an increase in exposure yields an increase in risk). *Magistrini v. One Hour Martinzing Dry Cleaning*, 180 F. Supp. 2d 584, 592-93 (D.N.J. 2002).

This case does not present the question whether a securities fraud case can be premised on nondisclosure of information establishing a causal inference on the basis of such criteria. Respondents instead focus on the mere nondisclosure of AERs involving Zicam use and anosmia. In their words, "a correct analysis of materiality on the facts alleged here asks whether a reasonable shareholder would consider it important that large numbers [sic] of Zicam users had lost their sense of smell." Opp. to Pet. for Cert. 12 (internal quotation marks omitted); *see id.* at 16 (identifying "specific information" that petitioners "failed to disclose" as injuries reported by "a number of Zicam users immediately after they used the product"); *id.* at 17 (noting "pointed complaints about Zicam-induced anosmia that petitioners received"); *id.* at 19 (emphasizing "the requisite *materiality* of the undisclosed Zicam injuries known to petitioners").

the importance of the principles discussed above. Even accepting that 23 is the correct figure and indulging the assumption that double and treble hearsay complaints represent satisfactory data, the mere fact of 23 AERs is nowhere close to statistically significant evidence that Zicam use causes anosmia.[23]

The 23 AERs cited by respondents were received over the course of four years—from 1999 to early 2004—when Matrixx sold literally *millions* of units of Zicam. *See generally* Matrixx Initiatives, Inc., Form 10-K Annual Report (Mar. 28, 2003) (Zicam Cold Remedy accounted for more than 70% of 2002 net sales of $23.5 million). What is more, the complaint fails to compare that trivially minuscule reported incident rate to the known incident rate of anosmia in the population—and in particular, in the population of people *who have colds*, and thus take remedies like Zicam. That omission is critical because an AER may simply reflect an adverse event that was *caused by the underlying condition*, not the drug used to treat that condition. *See* FDA, Good Pharmacovigilance, at 9 ("other factors, including the disease being treated . . . may cause the events to be reported"); *see also supra* note 3 (describing "confounding by indication"). The common problem of confounding by indication is a key reason *post hoc ergo propter hoc* assumptions by lay consumers are not accepted by researchers, regulators, or courts.

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[23] In fact, respondents themselves did not even contend otherwise below—their complaint does not in terms purport to plead statistically significant facts, and they did not amend their complaint to plead such facts when allowed to do so by the district court. Instead they appealed and argued that statistical significance simply is not required.

Indeed, one of the important functions of statistical analysis—when done properly—is to control for these effects, and thus to determine whether the adverse event is potentially caused by use of the product, and not something else also associated with product use. *See* Green et al., Reference Guide on Epidemiology, at 370.

This case exemplifies the point. Respondents' complaint notes the statement that the common cold is a leading factor affecting sense of smell, and that "the population most likely to use cold remedy products is already at an increased risk of developing anosmia." J.A. 78a (Compl. ¶ 38). While criticizing other statements, the complaint alleges no facts denying or contradicting the observation that Zicam users are members of the population *already* most likely to experience anosmia, as a result of the very condition for which they are taking Zicam. Nor could it—the causal link between anosmia and upper respiratory infections associated with the common cold is well-recognized.[24] The complaint's allegations thus amount to a textbook example of when and how a cofounding indicator can dramatically undermine any basis for inferring that an adverse event was caused by use of a product. *See Robinson*, 2010 WL 3156548, at *5; *supra* note 3. There is simply no conceivable basis on which to conclude that 23 inci-

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[24] *See* Mayo Clinic, *Loss of Smell (Anosmia)* (Feb. 2, 2009), *available at* http://www.mayoclinic.com/health/loss-of-smell/MY00408/DSECTION=causes; Anil Lalwani, Olfactory Dysfunction, *in* Current Diagnosis & Treatment in Otolaryngology—Head & Neck Surgery 240 (2d ed. 2007); Norman M. Mann, *Management of Smell and Taste Problems*, 39 Cleveland Clinic J. Med. 329, 330 (2002).

dents reported out of millions of uses were *caused by* Zicam, and *not* the condition for which Zicam was used.

To plead a complaint alleging a plausible basis for concluding that anosmia-related AERs were material, plaintiffs would at least need to allege facts establishing that the rate of reported incidents exceeded, by a statistically significant degree, the known rate of anosmia among people with the common cold. Plaintiffs do not and cannot allege such facts.[25]

Absent that kind of allegation, it is difficult to understand the nature of the disclosure obligation envisioned by plaintiffs. Suppose petitioners had received 20 reports rather than 23 or 21—would the nondisclosure be material? What if it were only 18? Do respondents believe the 12 reports counted by pe-

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[25] In their opposition to the petition for a writ of certiorari, respondents suggested that a statement made in November 2003 that Matrixx could "incur significant costs resulting from product liability claims," J.A. 177a, "shows that the truth behind petitioners' omissions and misleading denials would have been highly material to Matrixx investors." Opp. to Pet. for Cert. 21. Respondents make no effort to explain how a statement of the blindingly obvious—product-liability lawsuits can be costly—shows why a reasonable investor would want to know about 21 scientifically unreliable AERs, out of millions of units sold. Those reports themselves do nothing to show that Matrixx would actually be facing litigation *with a material impact on the company's finances*, which is the only potentially relevant point. And litigation impacts in any event are already governed by a separate disclosure duty, *see* Regulation S-K, 17 C.F.R. § 229.103, which is not implicated here. Neither the district court nor the court of appeals considered Matrixx's generic lawsuit-related statement a relevant aspect of the materiality analysis in this case. *See* Pet. App. 21a-26a, 44a-50a.

titioners would qualify as material? What about 11, or seven, or four? Or just one? Respondents cannot answer these questions. Apart from statistical significance, there is no intelligible basis on which petitioners—or a reasonable investor—could understand when and why anosmia-related AERs indicate that it is Zicam, and not the common cold for which people are taking Zicam, that is causing the rarely reported anosmia reactions.

II. FAILURE TO DISCLOSE UNRELIABLE ANECDOTAL INCIDENT REPORTS DOES NOT GIVE RISE TO A "STRONG INFERENCE" OF SCIENTER

Respondents also fail to plead with particularity specific facts that give rise to an inference that petitioners intended to deceive that is "cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *Tellabs*, 551 U.S. at 324.

Given the unreliability of mere AERs, and the fact that 12 or 21 or any number remotely close to that range does not show any statistically significant difference between Zicam users reporting anosmia and common cold sufferers experiencing anosmia, there is no basis for considering the inference of intentional deception to be at least as compelling as alternative inferences. Rather, the most obvious inference is that petitioners did not disclose the AERs simply because petitioners believed they were far too few, and too caught up with the confounding cold indicator, to indicate anything meaningful about adverse reactions to use of Zicam. *See Carter-Wallace II*, 220 F.3d at 40-42 (explaining that defendant's

awareness of statistically insignificant adverse event reports did not satisfy pleading requirement under Federal Rule 9(b)). Respondents plead nothing that would call that inference into doubt.

Especially given the "[e]xacting" requirements for pleading scienter imposed by the PSLRA, *Tellabs*, 551 U.S. at 313, an inference of scienter based upon scientifically unreliable AERs would be particularly inappropriate. Because the reports revealed no statistically significant association between Zicam use and anosmia, petitioners were faced simply with a handful of double and triple hearsay AERs from users already disproportionately susceptible to anosmia. Petitioners' "awareness of [AERs] that could have been random cannot lead to the conclusion" that petitioners acted with scienter, *Carter-Wallace II*, 220 F.3d at 42, in projecting further growth or in asserting that the allegations of a causal link between Zicam and anosmia were unfounded. These statements were entirely consistent with the FDA's and courts' assessment of the limited probative value of AERs. As the FDA explains, "[f]or any given [AER], there is no certainty that the suspected drug caused the [alleged adverse event]." FDA, 1996 Annual Report, at 2. That is why "[c]ase studies" reporting anecdotal evidence are by themselves generally "insufficient to show general causation." *Hendrix*, 609 F.3d at 1197. Respondents have not alleged facts sufficient to establish that the handful of AERs involved in this case demonstrate a causal link between Zicam and anosmia, much less specific facts that would support a strong inference that petitioners acted with scienter in not disclosing the AERs. *See* Adverse Event Reporting at 7. In-

deed, recognizing that unreliable AERs might be confused by many investors for meaningful evidence of causation—a common enough mistake among laypersons—petitioners may well have believed that disclosing the reports would have been *contrary* to their duty to avoid making misleading statements.

Respondents, in short, allege no facts establishing that the inference of scienter was at least as compelling as the obvious alternative: petitioners believed the handful of reports did not reveal any causal link that needed to be disclosed, and that disclosure would be more likely to mislead investors and consumers than to inform them.

CONCLUSION

For the foregoing reasons, the court of appeals' judgment should be reversed.

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APPENDIX

APPENDIX

Case Law Finding AERs And Case Reports To Be Unreliable Evidence Of Causation

Examples from Federal Case Law

1) *Allison v. McGhan Med. Corp.*, 184 F.3d 1300, 1316 (11th Cir. 1999) ("[C]asc reports and case studies are universally regarded as an insufficient scientific basis for a conclusion regarding causation because case reports lack controls.")

2) *Appleby v. Glaxo Wellcome, Inc.*, 2005 WL 3440440, at *3, *7 (D.N.J. Dec. 13, 2005) (AERs "may not be sufficiently reliable or relevant to be admissible on the issue of causation")

3) *Baker v. Chevron USA, Inc.*, 680 F. Supp. 2d 865, 886 (S.D. Ohio 2010) ("case studies must be viewed with caution")

4) *Benkwith v. Matrixx Initiatives, Inc.*, 467 F. Supp. 2d 1316, 1327, 1329 (M.D. Ala. 2006) (AERs are "are even less persuasive than case reports" because they are "[u]ncontrolled anecdotal information")

5) *Brumbaugh v. Sandoz Pharms. Corp.*, 77 F. Supp. 2d 1153, 1156 (D. Mont. 1999) (AERs "do not demonstrate a causal link but instead represent coincidence")

6) *Casey v. Ohio Med. Prods.*, 877 F. Supp. 1380, 1385 (N.D. Cal. 1995) ("case reports are not reliable scientific evidence of causation")

7) *Caraker v. Sandoz Pharms. Corp.*, 172 F. Supp. 2d 1046, 1050 (S.D. Ill. 2001) ("scant number of case reports indicating that [drug] is temporally associated" with adverse event cast doubt on reliability)

8) *Cloud ex rel. Cloud v. Pfizer, Inc.*, 198 F. Supp. 2d 1118, 1133, 1138 (D. Ariz. 2001) (AERs and "retrospective case reports" are "merely compilations of occurrences, and have been rejected as reliable scientific evidence supporting an expert opinion")

9) *Dellinger v. Pfizer Inc.*, 2006 WL 2057654, at *9 (W.D.N.C. July 19, 2006) ("[M]any courts have recognized that adverse drug reaction case reports and other regulatory reports fail to test a causal hypothesis and therefore cannot support a causation opinion.")

10) *DeLuca v. Merrell Dow Pharms., Inc.*, 791 F. Supp. 1042, 1050-51, 1057 (D.N.J. 1992) ("methodology" of relying upon AERs "produces inaccurate and unreliable results because such data are unreliable for determining causation")

11) *Dunn v. Sandoz Pharms. Corp.*, 275 F. Supp. 2d 672, 682 (M.D.N.C. 2003) ("Case reports are not scientific proof of causation")

12) *Ervin v. Johnson & Johnson, Inc.*, 2006 WL 1529582, at *6-*7 (S.D. Ind. May 30, 2006) ("Courts should treat with caution those expert opinions based on case reports.")

13) *Glastetter v. Novartis Pharms. Corp.*, 252 F.3d 986, 990 (8th Cir. 2001) ("case reports" suffer from numerous flaws and are "not scientifically valid proof of causation")

14) *Gibson v. Sanofi-Aventis U.S., LLC*, 2009 WL 3490454, at *7-*8 (W.D. Ky. Oct. 27, 2009) ("scant review of a number of case reports" insufficient to establish reliable causation opinion)

15) *Hagaman v. Merrell Dow Pharms.*, 1987 WL 342949, at *8 (D. Kan. June 26, 1987) ("inherent unreliability of the [AERs] requires this court to prohibit their use as a basis for causation")

16) *Haggerty v. Upjohn Co.*, 950 F. Supp. 1160, 1165 (S.D. Fla. 1996) (AERs have "inherent bias" and "cannot be relied upon to form causation opinions")

17) *Hendrix v. Evenflo Co.*, 609 F.3d 1183, 1197 (11th Cir. 2010) ("Case studies and clinical experience, used alone and not merely to bolster other evidence, are also insufficient to show general causation.")

18) *Hollander v. Sandoz Pharms. Corp.*, 289 F.3d 1193, 1211 (10th Cir. 2002) (case reports "contain only limited information" and are "unreliable evidence of causation")

19) *In re Accutane Prods. Liab. Litig.*, 2007 WL 1288354, at *3-*4 (M.D. Fla. May 2, 2007) (excluding AERs and causality assessments from evidence because they "reflect[] nothing more than an assessment of a possible relationship, not an actual relationship")

20) *In re Diet Drugs Prods. Liab. Litig.*, 2001 WL 454586, at *15 (E.D. Pa. Feb. 1, 2010) (AERs "are universally recognized as insufficient and unreliable evidence of causation")

21) *Leathers v. Pfizer, Inc.*, 233 F.R.D. 687, 694 (N.D. Ga. 2006) (AERs "generally do not, standing alone, render an expert's opinion reliable under *Daubert*")

22) *Lopez v. Wyeth-Ayerst Labs.*, 1996 WL 784566, at *4 (N.D. Cal. Dec. 13, 1996) ("Generally, courts have excluded expert causation testimony that is based upon . . . anecdotal or case reports")

23) *Lusch v. Matrixx Initiatives, Inc.*, 2007 U.S. Dist. LEXIS 72068, at *10-*11 (D. Or. Sept. 25, 2007) (excluding expert testimony based in part on case reports)

24) *Martinkovic v. Bangash*, 1987 WL 28400, at *2 (N.D. Ill. Dec. 18, 1987) ("Of course the anecdotal reports of alleged adverse reactions are not admissible to prove the truth of the matter declared in the reports")

25) *McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1250, 1254 (11th Cir. 2005) ("case reports raise questions, they do not answer them")

26) *Muzzey v. Kerr-McGee Chem. Corp.*, 921 F. Supp. 511, 519 (N.D. Ill. 1996) ("Anecdotal reports . . . are not reliable bases to form a scientific opinion about a causal link.")

27) *Nelson v. Am. Home Prods. Corp.*, 92 F. Supp. 2d 954, 969 (W.D. Mo. 2000) (AERs "do not demonstrate a causal link sufficient for admission to a finder of fact in court")

28) *Newton v. Roche Labs., Inc.*, 243 F. Supp. 2d 672, 680 (W.D. Tex. 2002) ("many other courts have soundly rejected case reports as an acceptable basis for causation")

29) *Richardson v. Richardson-Merrell, Inc.*, 649 F. Supp. 799, 801 & n.5 (D.D.C. 1986) (AERs "are neither exceptions to the hearsay rule nor data reasonably relied upon by experts in the field of making determinations of causality")

30) *Rider v. Sandoz Pharms. Corp.*, 295 F.3d 1194, 1199 (11th Cir. 2002) ("while they may support other proof of causation, case reports alone ordinarily cannot prove causation")

31) *Rose v. Matrixx Initiatives, Inc.*, 2009 WL 902311, at *11, *15 (W.D. Tenn. Mar. 31, 2009) (case studies "do not 'provide an adequate scientific basis for general causation'")

32) *Ryman v. Sec'y of Dep't of Health & Human Servs.*, 65 Fed. Cl. 35, 39-40, 43 (2005) ("Vaccine Adverse Event Reporting System . . . evidence is not reliable.")

33) *Saari v. Merck & Co.*, 961 F. Supp. 387, 398 (N.D.N.Y. 1997) (doctor's "report to the FDA was simply a report of what plaintiff told him about what she believed was her reaction to the vaccine")

34) *Salden v. Matrixx Initiatives, Inc.*, 2007 U.S. Dist. LEXIS 18552, at *6 (E.D. Mich. Mar. 16, 2007) (case reports are "merely anecdotal")

35) *Sutherland v. Matrixx Initiatives, Inc.*, 2006 U.S. Dist. LEXIS 96652, at *30 (N.D. Ala. Nov. 7, 2006) ("standing alone" case studies are insufficient "to establish general causation")

36) *Turner v. Iowa Fire Equip. Co.*, 229 F.3d 1202, 1209 n.5 (8th Cir. 2000) ("Case reports are generally not considered reliable evidence of causation.")

37) *Wade-Greaux v. Whitehall Labs., Inc.*, 874 F. Supp. 1441, 1453, 1470, 1481, 1483 (D.V.I. 1994) ("anecdotal information of chance associations . . . [has] no epidemiological significance")

38) *Willert v. Ortho Pharm. Corp.*, 995 F. Supp. 979, 981 (D. Minn. 1998) (case reports "do not investigate or explain the mechanism of causation" (internal quotation marks omitted))

39) *Wolf v. Procter & Gamble Co.*, 555 F. Supp. 613, 620 (D.N.J. 1982) (consumer complaints received by company are inadmissible hearsay)

40) *Wyatt v. Matrixx Initiatives, Inc.*, 2007 U.S. Dist. LEXIS 67986, at *14 (N.D. Ala. Mar. 30, 2007) (case study "amounts to anecdotal evidence, not evidence that has been vigorously tested using scientific methodology")

Examples from State Case Law

1) *Cosgrove v. Merrell Dow Pharms., Inc.*, 788 P.2d 1293, 1298-99 (Idaho 1989) (AERs "are anecdotal in nature and should not form the basis for any conclusions, expert or otherwise")

2) *Heckstall v. Pincus*, 797 N.Y.S.2d 445, 447 (N.Y. App. Div. 2005) (AERs are "unverified listings and reporting of adverse reactions" and "are not generally accepted in the scientific community on questions of causation")

3) *Linnen v. A.H. Robins Co.*, 2000 WL 16769, at *10 (Mass. Super. Dec. 14, 1999) ("[C]ase reports alone are not considered reliable scientific evidence of causation.")

4) *Merrell Dow Pharms., Inc. v. Havner*, 953 S.W.2d 706, 720-21 (Tex. 1997) ("[A]necdotal . . . evidence accomplishes no more than a false appearance of direct and actual knowledge of a causal relationship.")

5) *Pauley v. Bayer Corp.*, 2006 WL 463866, at *2 n.2 (Pa. C.P. Phil. Jan. 26, 2006) (AERs "are not proof of the data they contain, and do not directly bear upon the adequacy of label warnings")

6) *Pauling v. Orentreich Med. Grp.*, 787 N.Y.S.2d 311, 312 (N.Y. App. Div. 2005) (under both *Daubert* and *Frye*, "observational studies" by themselves are unreliable)

7) *Peters v. Johnson & Johnson Prods., Inc.*, 783 S.W.2d 442, 444-45 (Mo. Ct. App. 1990) (AERs are inadmissible hearsay as "unsolicited letters and unsubstantiated reports from alleged . . . users do not stand as to their trustworthiness")

8) *Ranes v. Adams Labs., Inc.*, 778 N.W.2d 677, 691-94 (Iowa 2010) (case reports "reflect only reported data, not scientific methodology")

9) *Revels v. Novartis Pharms. Corp.*, 1999 WL 644732, at *4-*5 (Tex. App. Aug. 26 1999) ("[A] study of case reports alone is a scientifically invalid manner in which to form an expert opinion.")

10) *Swallow v. Emergency Med. of Idaho, P.A.*, 67 P.3d 68, 73 (Idaho 2003) (reports of ten adverse events not reliable evidence of causation where "there is no showing that ten adverse cardiac events occurring over eight years to patients . . . is a greater incidence of such events than would be expected to occur by chance")

RESPONDENT'S BRIEF

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IN THE
Supreme Court of the United States

MATRIXX INITIATIVES, INC., ET AL.,
Petitioners,

v.

JAMES SIRACUSANO AND NECA-IBEW PENSION FUND,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

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QUESTION PRESENTED

Respondents are investors in petitioner Matrixx Initiatives, Inc. who claim that petitioners violated § 10(b) of the Securities Exchange Act of 1934 and Securities and Exchange Commission Rule 10b-5 by misrepresenting and by failing to disclose information about the safety of their drug products, including several independent reports by doctors linking intranasal applications of Matrixx's Zicam products to persistent anosmia (loss of the sense of smell).

Contrary to petitioners' question presented, which asserts that this case concerns "a pharmaceutical company's nondisclosure of adverse event reports even though the reports are not alleged to be statistically significant," this case does not involve "adverse event reports" required by the Food and Drug Administration. Zicam was not subject to the federal reporting requirements at the relevant time. *See infra* pp. 8-9, 55; Br. in Opp. 17-18.

Accordingly, the question presented is:

Whether a securities-fraud complaint adequately can plead materiality and scienter by alleging that defendants received multiple, credible reports from medical specialists that its cold medicine appeared to cause serious, persistent anosmia, omitted disclosure of product-liability litigation concerning that defect, obtained scientific studies linking the drug's key ingredient zinc to anosmia but conducted no follow-up studies, and stated that clinical trials established that its drug did not cause anosmia when in fact it had no basis for any such claim.

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INTRODUCTION

Since Justice Story's time, this Court has defined materiality in a wide variety of contexts as a totality-of-the-circumstances inquiry. In *TSC Industries, Inc. v. Northway, Inc.*, 426 U.S. 438 (1976), and *Basic Inc. v. Levinson*, 485 U.S. 224 (1988), this Court adopted that well-settled approach in cases of securities fraud. The inquiry essentially asks whether, in light of the context and circumstances, a reasonable investor would regard a statement or omission as important in making a decision to purchase or sell securities.

Respondents' complaint alleges that, by October 2003, petitioner Matrixx Initiatives, Inc. ("Matrixx") knew of a problem with its flagship drug Zicam. Zicam was a then-popular cold remedy earning millions of dollars per quarter, with rapidly growing sales. But Matrixx had received warnings from several specialists who had diagnosed certain Zicam products as causing a noteworthy number of patients to experience persistent anosmia – loss of the sense of smell. A link between Zicam and that very serious condition posed a major threat to Matrixx's business: it could lead to irreparable damage to the Zicam brand, from which Matrixx derived the predominant portion of its revenues; regulatory action against Matrixx; and costly product-liability suits. Indeed, in October 2003, the first of many suits against Matrixx already had been filed.

Matrixx responded to the warnings of a link between Zicam and anosmia by concealing them. Through baseless threats of legal action, it intimidated a group of medical specialists into removing Zicam's name from a presentation at a national conference. It issued optimistic statements that talked generically about possible product-liability litigation

without mentioning actual litigation already filed against the company. When, in February 2004, allegations that Zicam caused anosmia became public despite Matrixx's efforts, it stated misleadingly that the safety of Zicam had been "well established" by "clinical trials." JA77a-78a (¶ 38).[1] Days later, the doctor whom Matrixx had threatened went to the press with his information linking Zicam to anosmia, and Matrixx's stock dropped 23.8% in a day.

As Matrixx was forced only weeks later to admit, the evidence it had in February 2004 was insufficient (at best) to establish that Zicam was safe. Indeed, the Food and Drug Administration ("FDA") ultimately sent Matrixx a warning letter charging (among other things) that the Zicam products at issue were misbranded because their labeling failed to disclose the risk that they would cause anosmia. Matrixx pulled those products off the market.

Matrixx now seeks from this Court a rule that its statements and omissions in 2003 and 2004 could not, as a matter of law, have defrauded its investors. Matrixx maintains that, unless the number of cases of Zicam-induced anosmia known to Matrixx were statistically significant, no reasonable investor would have cared about the information Matrixx had, and Matrixx could not possibly have acted with scienter.

The unprecedented pleading standards urged by Matrixx would undermine governmental enforcement actions and private securities suits alike. Matrixx seeks to elevate an arbitrary threshold – statistical significance – into a rule of law pursuant to which

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[1] "JA__a (¶ __)" refers to paragraphs in the operative complaint, reproduced in the Joint Appendix. "App." refers to the appendix to the certiorari petition.

aggrieved investors in drug companies could never survive motions to dismiss unless they had a good-faith basis for pleading that the false statements or omissions rested on information that rose to the level of "statistical significance."

This Court should reject Matrixx's proposed standard. First, it conflicts with the well-settled understanding of materiality in a wide variety of legal contexts. Second, it distorts the uses and purposes of statistical significance, which does not equate to practical significance. Third, it creates a standard divorced from the behavior of actual and reasonable investors, who base investment decisions on a broad variety of useful information rather than limiting themselves to findings based solely on statistics. Fourth, it incentivizes manufacturers to withhold the necessary data from which a statistical analysis could be drawn. And, fifth, it promotes a battle-of-the-statistical-experts at the pleading stage of a case, rather than after factual development. The court below rightly rejected Matrixx's artificial, unworkable, and unprecedented bright-line rule. This Court should as well.

STATEMENT

A. Statutory And Doctrinal Background

Congress enacted the Securities Act of 1933 and the Securities Exchange Act of 1934 ("1934 Act") in response to widespread abuses in the securities industry. To advance the objective of "honest markets," *Basic*, 485 U.S. at 230 (internal quotations omitted), 1934 Act § 10(b) forbids the use of "any manipulative or deceptive device or contrivance" "in connection with the purchase or sale of any security." 15 U.S.C. § 78j(b).

Securities and Exchange Commission ("SEC") Rule 10b-5 implements § 10(b) by prohibiting "(a) . . . any device, scheme, or artifice to defraud, (b) . . . any untrue statement of a material fact or . . . omi[ssion of] a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading, [and] (c) . . . any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person." 17 C.F.R. § 240.10b-5. A private plaintiff seeking relief for a § 10(b) violation must show "(1) a material misrepresentation or omission by the defendant; (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance upon the misrepresentation or omission; (5) economic loss; and (6) loss causation." *Stoneridge Inv. Partners, LLC v. Scientific-Atlanta, Inc.*, 552 U.S. 148, 157 (2008).

The Private Securities Litigation Reform Act of 1995 ("PSLRA") requires that the complaint in a securities-fraud action alleging a material misstatement or omission "specify each statement alleged to have been misleading, [and] the reason or reasons why the statement is misleading," and provide a particularized basis for any allegations made on information and belief. 15 U.S.C. § 78u-4(b)(1). Where applicable, the complaint also must "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." *Id.* § 78u-4(b)(2). A "strong inference" is one that is "cogent and at least as compelling as any opposing inference of nonfraudulent intent." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 314 (2007).

The PSLRA does not impose any heightened pleading standard for allegations that a misstatement or omission was material. Materiality allegations are governed by Federal Rule of Civil Procedure 8(a)(2), which requires a civil complaint to contain "a short and plain statement of the claim showing that the pleader is entitled to relief."

B. Nature Of The Action

Respondents seek damages arising from petitioners' securities fraud from October 22, 2003, to February 6, 2004. JA60a (¶ 1). Respondents allege that, during that time, petitioners[2] were aware of important information linking intranasal Zicam products to persistent anosmia, but nevertheless made materially false and misleading statements and omissions concerning Zicam and anosmia that overstated Matrixx's likely future prospects. JA60a-64a (¶¶ 1-10), 98a-99a (¶¶ 58-60).

1. Intranasal application of zinc and anosmia

Zinc gluconate, the active ingredient of Matrixx's Zicam products, is a zinc salt. When dissolved, it releases positively charged zinc ions. *See Handbook of Applied Therapeutics* 2-9 (Mary Anne Koda-Kimble et al. eds., 8th ed. 2007).

Medical researchers long have known that zinc salts can destroy the sense of smell when applied to the olfactory region of the nasal cavity. That effect was first discovered in 1934, through efforts to combat polio. Researchers then believed that persons contracted the polio virus through inhalation into the olfactory cleft and then transmission along

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[2] Petitioners (collectively "Matrixx") are Matrixx itself and three Matrixx executives. JA65a (¶¶ 16-20).

the olfactory nerves to the victim's spinal cord.[3] The resulting medical mantra became "[p]rotect the nose and prevent polio." Roland H. Berg, *Polio and Its Problems* 38 (1948). Experiments began with various chemicals that might offer protection.

Stanford University researcher Edwin Schultz touted zinc sulfate (a zinc salt) as the "golden chemical" to protect the nose. *Id.* at 37. Schultz believed that zinc caused proteins in the nasal membranes to form a protective coating around the olfactory nerves, preventing them from absorbing the polio virus. *Id.* He further believed that zinc would not create that barrier "unless the protective spray had temporarily destroyed the sense of smell." *Id.* at 39.

Zinc-induced anosmia was not always temporary. During a 1937 polio epidemic in Toronto, Canada, nose-and-throat specialists sprayed some 5,000 children with a zinc sulfate solution. *Id.* at 40. Months later, Schultz began receiving complaints that many of the children "had suffered a complete and evidently permanent loss of the sense of smell." *Id.* at 42. Because the treatment also failed to stop polio, that ended the intranasal application of zinc sulfate in humans.

Animal studies continued on the effect of ionized zinc on the sense of smell. A 1976 *American Journal of Anatomy* article explained that exposing the olfactory epithelium[4] of mice to a zinc sulfate solution

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[3] *See* E.W. Schultz, *Immunity and Prophylaxis in Poliomyelitis*, 107 J. Am. Med. Ass'n 2102, 2103 (1936); E.W. Schultz & L.P. Gebhardt, *Zinc Sulfate Prophylaxis in Poliomyelitis*, 108 J. Am. Med. Ass'n 2182 (1937).

[4] The olfactory epithelium "lines the olfactory region of the nasal cavity and contains olfactory receptors." *Dorland's Illustrated Medical Dictionary* 644 (31st ed. 2007).

caused severe damage.[5] In 1978, researchers described the "immediate and total loss" of treated mice's ability to smell following nasal irrigation with zinc sulfate.[6] In 1993, researchers reported that applying a zinc sulfate spray to the olfactory mucosa in rats caused anosmia in 80% of the animals within two days.[7]

Studies also determined that the anosmia-inducing effect of zinc sulfate was specifically attributable to the *zinc ions* in the solution (as opposed to the sulfate ions). In 1972, researchers compared the effect of zinc sulfate on sea turtles to the effect of magnesium sulfate and found that only the former caused anosmia, concluding: "The role of Zn^{++} seems crucial." Marion Manton et al., *Chemoreception in the Migratory Sea Turtle* Chelonia Mydas, 143 Biol. Bull. 184, 193 (1972). In 1982, a researcher tested the effect of several salt solutions, including zinc sulfate and zinc chloride, on the olfactory mucosa of catfish. *See* Paul Cancalon, *Degeneration and Regeneration of Olfactory Cells Induced by $ZnSO_4$ and Other Chemicals*, 14 Tissue & Cell 717 (1982). He observed the presence of a "[s]pecific degeneration effect of Zn^{2+} ions" on the mucosa that did not depend on the compound's other chemicals. *Id.* at 729 ("[S]odium sulfate and sodium chloride leave the mucosa intact, [but] . . . zinc sul-

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[5] *See* Daniel H. Matulionis, *Light and Electron Microscopic Study of the Degeneration and Early Regeneration of Olfactory Epithelium in the Mouse*, 145 Am. J. Anat. 79 (1976).

[6] Joseph W. Harding et al., *Denervation of the Primary Olfactory Pathway in Mice*, 140 Brain Research 271, 271 (1978).

[7] *See* Anne D. Mayer & Jay S. Rosenblatt, *Peripheral Olfactory Deafferentation of the Primary Olfactory System in Rats Using $ZnSO_4$ Nasal Spray With Special Reference to Maternal Behavior*, 53 Physiol. & Behav. 587 (1993).

fate and zinc chloride are equally effective."). Thus, by at least the 1980s, substantial scientific evidence existed that ionized zinc applied intranasally could adversely affect the sense of smell.

2. Matrixx's intranasal zinc products

Matrixx develops, manufactures, and markets over-the-counter pharmaceuticals. JA60a (¶ 2). Matrixx's core brand in 2003-2004 was a line of common-cold products generating 100% of Matrixx's sales. *Id.* The "Zicam Cold Remedy" accounted for approximately 70% of Matrixx's sales overall. *Id.* The over-the-counter remedy had several forms, including an intranasal spray and gel. *Id.*

Matrixx marketed Zicam as a homeopathic[8] medicine. JA77a (¶ 38). Based on that characterization, Zicam did not undergo the rigorous new drug application process that "applie[s] to all other new drugs in the United States" and requires pre-market submission to the FDA of clinical testing data showing a drug's safety and efficacy. Suzanne White Junod, *An Alternative Perspective: Homeopathic Drugs, Royal Copeland, and Federal Drug Regulation*, 55 Food & Drug L.J. 161, 183 (2000); *see id.* (homeopathic regulation "stands in marked contrast to the well-honed new drug application/investigational new drug process"); *compare* 21 U.S.C. § 355 (governing new

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[8] Homeopathy is a type of alternative medicine based on the "principle . . . that a disease can be cured by a substance that produces similar symptoms in healthy people" and that involves "giving very small doses of highly diluted substances." National Ctr. for Complementary and Alternative Medicine, U.S. Dep't of Health & Human Services, *Homeopathy: An Introduction* 1, *available at* http://nccam.nih.gov/health/homeopathy/homeopathy.pdf (updated Aug. 2010). "[A] number of its key concepts are not consistent with the current understanding of science, particularly chemistry and physics." *Id.*

drug applications) *and* 21 C.F.R. pts. 310, 312, 314 (same) *with* FDA Compliance Policy Guide ("CPG") § 400.400, "Conditions Under Which Homeopathic Drugs May Be Marketed" (rev. Mar. 1995) (formerly CPG § 7132.15).

Between October 2003 and February 2004, manufacturers of drugs not marketed under an approved new drug application had no obligation to report to the government adverse events associated with their products. In 2006, Congress enacted the Dietary Supplement and Nonprescription Drug Consumer Protection Act, extending adverse event reporting requirements to such drugs. That Act now requires companies like Matrixx to submit to the government any report they receive of a "serious adverse event" – such as a death, hospitalization, disability, or birth defect – "associated with [their] drug." 21 U.S.C. § 379aa(a), (b).

3. Information communicated to Matrixx about Zicam and anosmia before February 2004

From before October 2003 through February 2004, Matrixx received credible, non-public information linking Zicam with persistent anosmia.

a. In 1999, Dr. Alan Hirsch, a practicing neurologist who specializes in issues of smell and taste, observed a link between Zicam use and anosmia in a "cluster" of his patients. JA67a (¶ 25). In December 1999, Dr. Hirsch called Matrixx to inquire about the amount of zinc in Zicam's nasal gel. JA67a-68a (¶ 25). He spoke with "a Mr. Laundau" and told him about at least one patient who had developed anosmia after using Zicam in the absence of a cold. JA68a (¶ 25). Dr. Hirsch further advised Laundau that studies had shown problems with the intranasal application of zinc. Laundau responded that he was

unaware of those studies. Dr. Hirsch volunteered to conduct a clinical study on a possible link between Zicam and anosmia, but Matrixx turned him down. *Id.*

b. Three years later, Matrixx contacted a researcher in the taste-and-smell field concerning Zicam. In September 2002, petitioner Timothy Clarot, Matrixx's Vice President of Research and Development, telephoned Dr. Miriam Linschoten of the University of Colorado's Health Sciences Center and Rocky Mountain Taste and Smell Center ("RMTSC"). JA68a (¶ 26). Dr. Linschoten was treating several patients at the RMTSC for loss of smell following Zicam use; one of them had complained to Matrixx. *Id.* Clarot told Dr. Linschoten that Matrixx had received additional, similar complaints from other Zicam users as far back as 1999. *Id.* Dr. Linschoten asked whether Matrixx had conducted relevant studies; Clarot replied that Matrixx had not, but had hired a consultant to review the product. JA68a-69a (¶ 26). Dr. Linschoten mentioned studies linking zinc sulfate to loss of sense of smell, but Clarot "gave her the impression that he had not heard of" such studies. JA69a (¶ 26).

On September 20, 2002, Dr. Linschoten e-mailed Clarot several abstracts of studies on zinc sulfate and anosmia. *Id.* (¶ 27). Clarot then invited Dr. Linschoten to participate in animal studies Matrixx was then planning, but she declined because her focus was on human research. *Id.*

c. In September 2003, Dr. Bruce Jafek of the Department of Otolaryngology[9] at the University of

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[9] Otolaryngologists are physicians specializing in "diseases and disorders of the ear, nose, throat (ENT), and related

Colorado School of Medicine, along with Dr. Linschoten and another colleague (JA101a (¶ 64)), developed a poster presentation[10] for the American Rhinologic Society[11] meeting on September 20, 2003. The presentation described the observed link between Zicam use and anosmia among numerous individuals. JA69a-70a (¶ 28).[12]

The presentation included a detailed case report on a 55-year-old man who, prior to using Zicam, had normal taste and smell functions. JA70a (¶ 28). Upon spraying Zicam into his nose, however, he experienced severe burning, followed immediately by the loss of his sense of smell. *Id.* By the presentation date, 23 months after the incident, the patient's sense of smell had not returned. The presentation noted nine other Zicam users with similar symptoms. *See* 2003 Presentation.

Dr. Jafek and his colleagues considered and rejected the possibility that the common cold itself had caused the subjects' anosmia. That phenomenon

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structures of the head and neck." American Academy of Otolaryngology, http://www.entnet.org/healthinformation/AboutOtolaryngology.cfm.

[10] Poster presentations are "a major format for communicating at scientific meetings." Martha Davis, *Scientific Papers and Presentations* 191 (2005).

[11] The American Rhinologic Society is "the world's largest physician organization whose mission focuses upon the medical and surgical treatment of patients with diseases of the nose and paranasal sinuses." American Rhinologic Society, http://www.american-rhinologic.org/.

[12] Matrixx has filed copies of the presentation ("2003 Presentation") in several district court proceedings, including *Hans v. Matrixx Initiatives, Inc.*, No. 3:04-cv-540-TBR (W.D. Ky. filed Feb. 1, 2006) (Dkt. No. 26-19). A more legible copy (provided by Dr. Linschoten) is enclosed in the back pocket herein.

(known as "post-viral anosmia") typically occurs following a *severe* upper respiratory infection ("URI"). The Zicam users discussed in the presentation typically took Zicam "early in the course of a *mild* URI." *Id.* (emphasis added). "Most convincing" in excluding the possibility of post-viral anosmia, the users described "immediate, acute, 'burning' pain" following Zicam use, "followed immediately by persistent hyposmia or anosmia." *Id.*[13]

Before the September conference, Matrixx received the presentation's abstract, which was entitled "Zicam® Induced Anosmia." JA69a (¶ 28). Matrixx sent two warning letters to Dr. Jafek seeking to prevent him from naming either Matrixx or Zicam. JA61a (¶ 4) (asserting that "'as a legal matter' he did 'not have [Matrixx's] permission to use their company name or product trademarks'" in the presentation); *see also* JA70a (¶ 29). Dr. Jafek redacted the Zicam name from the presentation. JA70a (¶ 29).

d. Personal-injury lawsuits also were filed against Matrixx by Zicam users. Between October 2003 and February 2004, 10 Zicam users sued Matrixx, alleging that Zicam had damaged their sense of smell. JA87a-88a (¶ 49) (listing complaints). From late 2003 through October 2004, more than 270 others sued Matrixx, alleging that Zicam had damaged their sense of smell. JA87a-91a (¶ 49). Matrixx since has settled some 300-plus Zicam lawsuits for approximately $12 million. Another 176 suits brought by 671 plaintiffs remained pending in May 2010.[14]

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[13] "Hyposmia" is a diminished or reduced sense of smell. *See Dorland's Illustrated Medical Dictionary* at 918.

[14] *See* Ken Alltucker, *High court to hear suit of investors vs. drug firm*, Ariz. Republic, June 15, 2010, at A1.

4. Statements by Matrixx to its investors from October 2003 to February 2004

a. In late October 2003, Matrixx announced that the Zicam brand was "poised for growth" in the upcoming cough-and-cold season. JA72a (¶ 32). Matrixx represented that it had "very strong momentum" because of the Zicam line – "[a] product that offers a unique benefit." JA73a-74a (¶ 33). Matrixx further said that it was "extremely well positioned for a successful" cold season and that annual revenues were poised to rise dramatically, "up in excess of 50%." JA74a (¶ 34). Matrixx disclosed nothing about the potential link between Zicam and anosmia, despite the information it had received. JA71a-75a (¶¶ 32-34).

b. On November 12, 2003, Matrixx filed its third-quarter 2003 Form 10-Q with the SEC. JA75a-76a (¶ 35). Matrixx included a statement about adverse reputational and financial consequences from product-liability claims, "even [those] without merit" and those "not proven to be valid." *Id.* Although a lawsuit alleging that intranasal Zicam caused anosmia had been filed on October 14, 2003, JA61a-62a (¶ 5), Matrixx disclosed neither that lawsuit's existence nor any other information about a possible link between intranasal Zicam and anosmia.

c. When news of a possible link between Zicam and anosmia reached the public in early 2004, Matrixx's stock price dropped significantly. On Friday, January 30, 2004, after ordinary trading closed, the Dow Jones Newswires reported that the FDA was looking into complaints that "an over-the-counter common-cold medicine manufactured" by Matrixx "may be causing some users to lose their sense of smell." JA79a-80a (¶ 40). Matrixx's stock price

dropped from $13.55 per share on January 30 to $11.97 per share on Monday, February 2. JA80a (¶ 41).

On February 2, Matrixx responded with a press release proclaiming Zicam's safety. JA77a-78a (¶ 38), 193a. Matrixx claimed that "alleg[ations] that intranasal Zicam products cause anosmia (loss of smell) are *completely* unfounded and misleading." JA77a (¶ 38) (emphasis added). Matrixx also reassured investors that "[i]n no clinical trial of intranasal zinc gluconate gel products has there been a single report of lost or diminished olfactory function (sense of smell). Rather, the *safety* and efficacy of zinc gluconate for the treatment of symptoms related to the common cold have been *well established* in two double-blind, placebo-controlled, randomized clinical trials." JA77a-78a (¶ 38) (emphases added). Following Matrixx's denials, its stock price rose to $13.40 on February 3. JA80a (¶ 41).

Matrixx suggested to its investors that reports of Zicam-induced anosmia could be explained as post-viral anosmia resulting from the common cold. JA78a (¶ 38); *see also* Pet. Br. 8-9 n.3. It did not disclose that the doctors whose research gave rise to those reports had specifically ruled out post-viral anosmia. *See supra* pp. 11-12.

d. On February 6, 2004, the link between Zicam and anosmia was revealed to a nationwide television audience. On the news program *Good Morning America* ("*GMA*") that day, reporter John Ferrugia told viewers about a woman named "Linda" who claimed that Zicam had caused her anosmia. JA80a (¶ 42). Ferrugia noted that Linda's claim was not an isolated one: "Dr. Bruce Jafek has discovered more than a dozen patients with the same troubles as

Linda . . . after using the Zicam product." *Id.* The reporter stated that four lawsuits had been filed alleging that Zicam caused anosmia and that "[o]thers are being prepared, anywhere from California to Michigan." JA81a (¶ 42).

Matrixx responded with more denials, issuing a press release that same day entitled "Matrixx Initiatives *Reaffirms Safety* of Intranasal Zicam® Remedy." JA81a (¶ 44), 201a (emphasis added). It repeated that in "no clinical trial of intranasal zinc gluconate gel products has there been a single report of lost or diminished olfactory function (sense of smell)." JA81a-82a (¶ 44).

Following the *GMA* broadcast, Matrixx's common stock plummeted, dropping 23.8% in one day (from $13.05 per share to $9.94) on unusually heavy trading volume. JA81a (¶ 43).

5. Subsequent developments

On February 27, 2004, Matrixx told the SEC and its investors that, in fact, it did not know whether Zicam could cause anosmia. JA82a (¶¶ 45-46), 206a.[15] In a Form 8-K filing, Matrixx admitted for the first time that it had convened a two-day meeting of "physicians and scientists to review current information on smell disorders" in response to "a poster presentation at the American Rhinologic[] Society in September 2003." JA82a (¶ 45). The panel found "insufficient scientific evidence at this time to determine if zinc gluconate, when used as recommended, affects a person's ability to smell." *Id.* (¶ 46). A contempora-

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[15] The complaint states that the Form 8-K filing took place on February 19, 2004. JA82a (¶¶ 45-46). The filing itself is dated February 27, but states that an event (presumably, the meeting) it is disclosing took place on February 19. JA205a.

neous ABC News report summarized the situation: "All along, Matrixx Initiatives, the maker of Zicam, said the product was safe. But now it admits there are no studies dealing with the issue." JA84a (¶ 47).

In mid-2004, Dr. Jafek and his colleagues expanded the 2003 Presentation into a peer-reviewed article published in the *American Journal of Rhinology*, then the American Rhinologic Society's official journal. JA101a (¶ 64).[16] An additional peer-reviewed study published in 2006 described 17 additional cases of anosmia observed at the University of California San Diego Nasal Dysfunction Clinic, concluding that 15 were caused by intranasal application of zinc gluconate.[17] More peer-reviewed articles studying zinc gluconate and anosmia have since been published.[18]

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[16] The district court refused to consider this article because it was "published post-Class Period." App. 42a; *see also* App. 19a n.4 (court of appeals did "not disturb" that ruling). Respondents have argued at every stage of this case that the district court erred in that ruling. The pertinent legal question is only whether respondents have *plausibly* alleged materiality. After-the-fact corroboration of a statement is relevant to that limited question, regardless of whether that corroboration would be admissible at trial. *See infra* p. 31. Matrixx itself invokes (at 7 n.2) post-Class-Period facts to question Dr. Jafek's credibility, including his later expert testimony in product-liability cases involving Zicam and court rulings excluding that testimony from evidence.

[17] *See* Thomas H. Alexander & Terence M. Davidson, *Intranasal Zinc and Anosmia: The Zinc-Induced Anosmia Syndrome*, 116 Laryngoscope 217, 218 (2006).

[18] *Compare* Burton Slotnick et al., *Olfaction and Olfactory Epithelium in Mice Treated With Zinc Gluconate*, 117 Laryngoscope 743, 746-47 (2007) (study funded in part by Matrixx, concluding that zinc gluconate did not cause long-lasting anosmia in mice), *with* Jae H. Lim et al., *Zicam-Induced Damage to*

On June 16, 2009, the FDA issued a warning letter to Matrixx, finding that several Zicam intranasal products "may pose a serious risk to consumers who use them." JA268a.[19] The FDA had received "more than 130 reports of anosmia . . . associated with use of these products." *Id.* In addition to those reports, the FDA was "aware that Matrixx appears to have more than 800 reports related to loss of sense of smell associated with Zicam Cold Remedy intranasal products." JA272a. The FDA found that Matrixx's Zicam intranasal products were misbranded for lack of "adequate warnings regarding the risk of anosmia associated with the product." JA271a.

The letter further stated that the FDA was "not aware of any data establishing that the Zicam Cold Remedy intranasal products are generally recognized as safe and effective for the uses identified in their labeling." JA269a. "On the contrary," the FDA concluded, "there is evidence that these products pose a serious safety risk to consumers," including "evidence in the published scientific literature that various salts of zinc can damage olfactory function in animals and humans." JA269a, 270a.

The letter noted that, although intranasal Zicam was labeled as homeopathic, it could not benefit from the FDA's discretionary enforcement guidelines regarding homeopathic products because "there [was]

Mouse and Human Nasal Tissue, 4 PLoS One e7647, at 5-8 (2009) (study whose authors declared they had no conflicts of interest, concluding that Zicam's effects "contributed to a long-lasting and apparently irreversible olfactory dysfunction in the mouse" and had toxic effects on human nasal tissue).

[19] *See* http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm166909.htm, *reprinted at* JA267a-274a ("Warning Letter").

evidence of a safety risk associated with the product." JA270a. The FDA has since described its letter as an "enforcement action to protect consumers from fraudulent alternative medicine products."[20]

After receiving the Warning Letter, Matrixx withdrew from the market its intranasal Zicam products.[21]

C. District Court Proceedings

On April 29, 2004, the first complaint in this action was filed. On March 4, 2005, lead plaintiff NECA-IBEW Pension Fund filed the operative consolidated amended complaint. JA59a-111a. Matrixx moved to dismiss. The district court granted the motion.

Relying upon *In re Carter-Wallace, Inc. Securities Litigation*, 220 F.3d 36 (2d Cir. 2000) ("*Carter-Wallace II*"), the court concluded that, unless Matrixx had known of "statistically significant" information linking Zicam to anosmia, all other information Matrixx had received on that topic was immaterial as a matter of law. App. 44a-50a. The court also held that respondents had not pleaded sufficiently that Matrixx had a "motive" to omit the truth about Zicam, "disbelieved" its public statements about Zicam, or had attempted to "profit" from them. App. 51a-52a. Finally, the court ruled that, unless respondents could show that Matrixx "*knew* there was a definitive and statistically significant

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[20] FDA, *Alternative Medicine Fraud*, http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/MedicationHealthFraud/ucm207747.htm (last updated Oct. 25, 2010).

[21] *See* Matrixx Initiatives, Inc., *Message to Consumers*, http://www.zicam.com/messagetoconsumers.

link between Zicam and anosmia," any amendment would be futile. App. 54a.

D. The Ninth Circuit's Decision

The Ninth Circuit reversed. It reasoned that *Basic* "rejected the adoption of a bright-line rule to determine materiality because '"[t]he determination [of materiality] requires delicate assessments of the inferences a 'reasonable shareholder' would draw from a given set of facts and the significance of those inferences to him."'" App. 23a (quoting *Basic*, 485 U.S. at 236 (quoting *TSC*, 426 U.S. at 450)) (alterations in original). Courts assessing materiality should engage in a "'fact-specific inquiry.'" *Id.* (quoting *Basic*, 485 U.S. at 240).

Rather than focusing solely on statistical significance, the court continued, a materiality analysis should consider whether reasonable investors would have viewed as significant the information about a Zicam-anosmia link that had been communicated to Matrixx. App. 24a-26a. The court held that respondents' allegations met the PSLRA's pleading standards, as well as the "plausib[ility]" standard of *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007). App. 26a.

The Ninth Circuit also reversed the district court's scienter holding, listing allegations supporting a strong inference of Matrixx's scienter. App. 28a-33a. By the time of its October 22, 2003 press release and conference call, Matrixx already had received information about a possible link between Zicam and anosmia from Drs. Hirsch, Linschoten, and Jafek. App. 28a-29a. Further, although Matrixx spoke about the reputational and financial risks of potential product-liability claims in its November 2003 Form 10-Q "in the abstract," Matrixx gave no indication

that the risk already had come to fruition (App. 30a), through the filing of a lawsuit.

By the time of Matrixx's February 2, 2004 press release,

> a strong inference can be drawn that [petitioners] knew that the statements alleging a link between Zicam and anosmia were not "completely unfounded and misleading." [Petitioners] allegedly knew about the presentation by Jafek to the American Rhinologic Society, Clarot's conversation with Linschoten, and several lawsuits alleging that Zicam caused anosmia.

App. 31a. In addition, Matrixx's statements in that press release that Zicam's safety had been "well established" by clinical trials conflicted with allegations that

> Clarot told Linschoten in September 2002 that Matrixx had not conducted any studies and asked her to participate in studies. The references in the press release to clinical trials establishing Zicam's safety also conflict with the March 4, 2004, news report that Matrixx did not know if Zicam could cause anosmia and [had] formed a medical advisory panel to conduct studies.

Id.

Viewing respondents' allegations as a whole, the Ninth Circuit concluded that they supported a scienter inference that was "'cogent and at least as compelling' as any 'plausible non-culpable explanation[]'" for petitioners' conduct. App. 33a (quoting *Tellabs*, 551 U.S. at 324) (alteration in original).

SUMMARY OF ARGUMENT

I.A. The standard for materiality in securities-fraud cases is well-settled. Under *TSC* and *Basic*, that standard is a fact-specific inquiry into the likelihood that a reasonable investor would "view[] . . . [particular information] as having significantly altered the 'total mix' of information . . . available." *TSC*, 426 U.S. at 449. It involves the drawing of delicate inferences and is usually a question for the finder of fact. The fact-specific nature of the materiality standard in fraud cases dates back at least to *McLanahan v. Universal Insurance Co.*, 26 U.S. (1 Pet.) 170, 189 (1828), and *McLanahan* itself treated the point as settled by even earlier authority. Materiality is similarly fact-specific in numerous other areas of the law.

B. Applying that settled materiality standard here compels the conclusion that respondents have stated a claim. In pleading materiality, respondents were required by *Twombly* and *Ashcroft v. Iqbal*, 129 S. Ct. 1937 (2009), only to establish a plausible inference of materiality. They did so by pointing to facts including, among others, the expert physicians who had concluded, by October 2003, that a causal link existed between intranasal Zicam use and persistent anosmia; the seriousness of persistent anosmia and the threat it posed to Zicam as Matrixx's principal revenue source; and the actual movements of Matrixx's stock price after the truth came out on February 6, 2004.

Matrixx's responses rely almost entirely on its request that this Court impose a bright-line rule requiring statistical significance for *any* allegation of a failure to disclose information about adverse drug effects to be material under the securities laws.

When that position fails (as it must), respondents should prevail. Matrixx also argues that the doctors who linked Zicam to anosmia in 2003 failed to account for "confounding factors" such as the common cold itself, but the doctors considered and rejected that theory.

C. Respondents also alleged facts sufficient to raise a strong inference of scienter, as required by the PSLRA and *Tellabs*. Matrixx's acts demonstrate that it either intended to deceive or acted recklessly with regard to the truth of its statements. Particularly convincing are its attempt in September 2003 to conceal from the public the presentation to the American Rhinologic Society through baseless legal demands that Dr. Jafek not use its name, and its claim in February 2004 that Zicam already had been proved safe before admitting, a few weeks later, that it had no basis to say one way or the other whether Zicam caused anosmia.

II.A. This Court should reject Matrixx's proposed bright-line rule that would require a showing of statistical significance in all cases involving adverse drug events. Statistical significance is not the same as practical importance, and practical importance is what matters for materiality.

B. *Basic* forecloses a rule that would make any fact, including statistical significance, a categorical prerequisite for materiality in securities-fraud cases. Such a rule would exclude information that a reasonable investor would consider important, and the filtering function of materiality does not permit such a result. Matrixx's argument that disclosure of statistically insignificant information will mislead investors is paternalistic and inconsistent with *Basic*'s core reasoning. The nationwide securities market is

served by many sophisticated analysts and advisors who are fully capable of understanding statistical nuance.

The cases on which Matrixx relies do not help it. The Second and Third Circuit cases did not address the materiality of non-statistical information, such as the expert physicians' opinions present here. Matrixx's other cases all involve the use of statistical significance at the *evidentiary* stages of a case, rather than at the pleading stage. Cases involving use of statistical significance in *proving* causation are inapposite when the question is whether a company has concealed information showing a material increase in the *risk* that causation at some future time would be proved.

C. Depending on the particular facts, a reasonable investor would pay attention to non-statistical evidence of risks to a company's drug products and to statistical evidence that provides useful information even without achieving a standard of "statistical significance." Both types of information have been accepted by courts in appropriate cases.

The argument that statistical evidence is meaningless unless found to be "significant" is based on an incorrect view of statistics. Courts and respected scholars have criticized the overuse of statistical significance: the better approach takes into account the estimated size and practical importance of a possible statistical relationship, rather than focusing solely on the precision of the estimate.

Matrixx's proposed rule has other defects. That rule would not lead to the certainty and determinacy that Matrixx promises because Matrixx shies back from selecting a particular critical value for testing significance, and because Matrixx and its *amici*

suggest leaving open significant exceptions to their proposed standard. Matrixx's rule also would impose unworkable burdens preventing investors from recovering on meritorious claims.

D. Finally, Matrixx mischaracterizes this case by suggesting that it concerns regulatory adverse event reports. The information at issue here was not the product of the FDA's Adverse Event Reporting System ("AERS"), which did not apply to Zicam at the time. Accordingly, Matrixx's arguments that regulatory adverse event reports are unreliable as a class are irrelevant. Also, because regulatory adverse event reports already are made public by the FDA, Matrixx's claim that releasing them will overwhelm the market with information has no weight.

The correct approach under *Basic* looks to whether the particular facts surrounding an adverse event report or group of such reports are material. When properly applied, that test presents no greater difficulty than any other totality-of-the-circumstances inquiry. The Ninth Circuit correctly applied that test, and this Court should affirm its judgment.

ARGUMENT

I. THE COMPLAINT ADEQUATELY PLEADS MATERIALITY AND SCIENTER

A. Materiality Is A Fact-Intensive Determination Based On The Totality Of The Circumstances

1. The long-settled standard for materiality in securities-fraud cases asks whether the misstated or omitted fact "would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available." *TSC*, 426 U.S. at 449; *see also Basic*, 485 U.S. at 232 (adopting *TSC*'s standard for Rule 10b-5 cases). That standard requires consideration of all other information that would have been available to the investor. Its purpose is "to filter out essentially useless information that a reasonable investor would not consider significant, even as part of a larger 'mix' of factors to consider in making his investment decision." *Basic*, 485 U.S. at 234.[22]

The materiality standard thus requires "delicate assessments of the inferences a 'reasonable shareholder' would draw from a given set of facts and the significance of those inferences to him." *TSC*, 426 U.S. at 450; *see also Basic*, 485 U.S. at 236 (quoting *TSC*). "[T]hese assessments are peculiarly ones for the trier of fact." *TSC*, 426 U.S. at 450. Both *TSC* and *Basic* were unanimously decided and have been the law for decades. Matrixx does not argue that

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[22] The standard is the same for common-law misrepresentation, where the test for materiality "cannot be stated in the form of any definite rule, but must depend upon the circumstances of the transaction itself." W. Page Keeton et al., *Prosser and Keeton on the Law of Torts* § 108, at 753 (5th ed. 1984).

either opinion is unworkable or should be revisited now.

2. Precedent dating back centuries confirms that the materiality of an allegedly fraudulent misstatement or omission is to be decided "in the particular case . . . upon its own circumstances." *McLanahan*, 26 U.S. (1 Pet.) at 189. In *McLanahan*, Justice Story discussed in detail the "inquisition into facts" needed to determine whether an omission concerning the time at which a ship sailed was material to an insurance contract. *Id.*[23] The Court held that the facts bearing on this inquiry should be found by the jury after hearing witness testimony. *See id.* at 191 (citing *Maryland Ins. Co. v. Ruden's Administrator*, 10 U.S. (6 Cranch) 338, 339-40 (1810); *New-York Firemen Ins. Co. v. Walden*, 12 Johns. 513 (N.Y. Sup. Ct. 1815) (Kent, Ch.)).

This Court has applied the venerable principle that materiality is fact-specific to more modern cases in a variety of subject areas. In *United States v. Gaudin*, 515 U.S. 506 (1995), for example, this Court applied *TSC*'s and *McLanahan*'s discussion of the factfinder's role to the materiality standard in a criminal prosecution for making false statements to the government: "[O]ur cases have recognized . . . that the materiality inquiry, involving as it does 'delicate assessments of the inferences a "reasonable [decision-

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[23] Relevant circumstances included "the nature and length of the voyage, the season of the year, the prevalence of the winds, the conformation of the coasts, the usages of trade as to navigation, and touching and staying at port, the objects of the enterprise and other circumstances, political and otherwise, which may retard or advance the general progress of the voyage," all considered in light of "nautical skill, information, and experience." *McLanahan*, 26 U.S. (1 Pet.) at 188.

maker]" would draw from a given set of facts and the significance of those inferences to him . . . [is] peculiarly on[e] for the trier of fact.'" *Id.* at 512 (quoting *TSC*, 426 U.S. at 450) (third through sixth alterations in original).

Similarly, in *Burlington Northern & Santa Fe Railway Co. v. White*, 548 U.S. 53 (2006), this Court described the highly contextual nature of the materiality inquiry for employment discrimination retaliation, noting that "the significance of any given act of retaliation will often depend upon the particular circumstances" and "an act that would be immaterial in some situations is material in others." *Id.* at 69 (internal quotations omitted).

3. To survive a motion to dismiss on materiality grounds under the standards announced by this Court in *Twombly* and *Iqbal*, respondents must satisfy the ordinary requirements of Federal Rule of Civil Procedure 8 by showing that their claims are plausible. *See Iqbal*, 129 S. Ct. at 1949 ("To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'") (quoting *Twombly*, 550 U.S. at 570).

In 1995, when Congress imposed higher pleading standards for allegations of falsity and scienter, *see* 15 U.S.C. §§ 78u-4(b)(1) (falsity), 78u-4(b)(2) (scienter), it did not heighten the standard for allegations of materiality. Congress's decision not to heighten the pleading standard for materiality conveys its intent that existing law (under *Basic* and *TSC*) should continue undisturbed, so that materiality remains a fact-intensive question generally to be decided on the evidence, not on the pleadings. *Cf. Patterson v. McLean Credit Union*, 491 U.S. 164, 172-73 (1989)

(statutory *stare decisis* has "special force" because "Congress remains free to alter what we have done").

B. The Complaint Plausibly Alleges That Matrixx Misstated And Omitted Material Facts

1. The complaint's factual allegations meet the foregoing materiality standard. The complaint alleges that Matrixx had undisclosed information in its possession that sufficiently suggested an important risk to its vital Zicam product line. That information was sufficiently significant to be material from a reasonable investor's perspective. Yet Matrixx withheld that information from its investors and made affirmative false and misleading statements about it.

a. By October 2003, the information in Matrixx's possession more than plausibly suggested a link between intranasal Zicam use and persistent anosmia. Matrixx received specific information from multiple reliable medical sources in 1999, 2002, and 2003. JA67a-70a (¶¶ 25-28). Nasal specialists had identified a causal link between intranasal Zicam use and persistent anosmia in multiple patients. Those identifications were not based on a mere correlation of Zicam use with anosmia. Rather, each doctor had found clinical evidence supporting the link. In particular, the patients who had experienced anosmia also reported a specific burning sensation immediately following intranasal Zicam use. JA69a-70a (¶ 28), 70a-71a (¶ 30).

A reasonable investor would have been particularly concerned about the specific information received by Matrixx because background medical research indicated a biologically plausible causal mechanism for a link between intranasal Zicam use and persistent anosmia. Numerous studies from as far back as the

1930s established that intranasally applied zinc could cause anosmia. Matrixx received information about such studies as early as 1999. *See supra* pp. 9-12.[24] Knowledge of those studies would have made a reasonable investor alert to the likelihood that the specific information Matrixx had received reflected a real problem for the company.

Dr. Jafek and his colleagues considered the clinical evidence of a causal link sufficient to justify a presentation to the American Rhinologic Society, a leading medical association for nasal specialists. JA69a-70a (¶ 28). Their findings were later published in the Society's peer-reviewed *American Journal of Rhinology*. Matrixx knew of Dr. Jafek's research findings, but responded only by sending letters improperly demanding that the presentation reference neither the company nor its products. JA70a (¶ 29); *see infra* note 32 (explaining why Matrixx's demand was baseless). Matrixx also knew by October 2003 that it had been sued based on allegations that Zicam caused anosmia. JA87a (¶ 49).[25]

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[24] Matrixx argues (at 6-7) that the relevant studies involved zinc sulfate, not the zinc gluconate used in Zicam. But scientists' "work with fish in the early [19]80s," JA69a (¶ 27), established that the harmful effects on sense of smell were caused by positive zinc ions. *See supra* p. 8. Reference 6 of the 2003 Presentation cited that research.

[25] Matrixx argues (at 48 n.25) that the product-liability suit already underway in October 2003 was irrelevant to materiality and that the Ninth Circuit did not rely on that suit in its materiality analysis. On the contrary, that court properly considered the undisclosed suit as one of many facts supporting respondents' plausible allegations of material omissions, as well as giving the nondisclosure considerable weight in its scienter analysis. *See* App. 25a-26a, 29a-30a. A reasonable investor would see a difference between Matrixx's generic disclosure that

b. Persistent anosmia is a very serious medical condition.[26] A link between anosmia and intranasal Zicam use would more than plausibly expose Matrixx and its investors to three risks: costly product-liability litigation against Matrixx, some of which was already underway (though undisclosed by Matrixx to investors); future FDA enforcement action; and drastically reduced sales of intranasal Zicam products, as well as reduced sales of other Zicam products through damage to the Zicam brand. The risk of reduced sales was especially acute because many consumers would not buy a cold remedy that could lead to a problem far more serious than the cold itself. The importance of those risks makes it more than plausible that information about a link between intranasal Zicam and anosmia would have been substantially likely to alter the total mix of information available to Matrixx's investors, particularly in light of Matrixx's reliance on its Zicam product line for the lion's share of its revenues.

c. The movements in Matrixx's share price after disclosure of the information linking Zicam to persistent anosmia further support the plausible materiality of Matrixx's misstatements and omissions. After *Good Morning America* reported on the connection between Zicam and persistent anosmia on February 6, 2004, the price of Matrixx's common stock dropped

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product-liability suits *can* happen and the fact that one already was underway. Further, the materiality of the suit lay not in the effect it individually would have on Matrixx's finances, but in its early indication that Matrixx's flagship drug was now exposed to litigation.

[26] *See* Warning Letter at JA274a n.2 ("[L]oss of sense of smell can have serious consequences. For example, patients with anosmia may not be able to detect the smell of a gas leak, smoke, or spoiled food.").

23.8% on unusually heavy trading volume, from $13.05 per share to $9.94. JA81a (¶ 43). That drop was not a temporary reaction to bad publicity, but a considered market judgment. Not until November 2004 did Matrixx's share price return to $13.05 per share.[27]

d. The FDA's later decision to send Matrixx the Warning Letter, which led Matrixx to remove intranasal Zicam from the market, further supports the plausible materiality of Matrixx's misstatements and omissions. The Warning Letter found that intranasal Zicam was misbranded because its labeling still, in 2009, did not mention the risk that it might cause anosmia. The letter echoed points that Dr. Jafek and his colleagues had made in late 2003; it also relied on additional information to which Dr. Jafek did not have access. *See supra* pp. 17-18.

The FDA's action in 2009 – based on a theory very similar to that of Dr. Jafek and the other doctors that notified Matrixx of the link between Zicam and anosmia between 1999 and 2003 – tends to corroborate those doctors' analysis, as do the later peer-reviewed publications on the topic. Wholly apart from the admissibility of that information as *evidence* of materiality (which respondents need not yet produce), these are among the "facts . . . suggestive enough to render [it] plausible," *Twombly*, 550 U.S. at 556, that the doctors had identified a serious problem that would have influenced a reasonable investor at the time.

e. In addition to omissions of material information, Matrixx made affirmative claims that Zicam

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[27] *See* Supplemental Request for Judicial Notice, Exh. A, No. 06-15677 (9th Cir. filed June 8, 2009).

had been proved safe. Those statements created a materially misleading impression because of the sparse and cursory nature of the testing that Matrixx had in fact conducted on Zicam. On February 2, 2004, after published reports of the Zicam-anosmia connection, Matrixx went so far as to say that the "safety" of Zicam had been "well established in two double-blind, placebo-controlled, randomized clinical trials." JA77a-78a (¶ 38). That press release purported to rebut "alleg[ations] that intranasal Zicam products cause anosmia" as "completely unfounded and misleading." *Id.* Matrixx's unmistakable intent in issuing its statement was to persuade investors that Matrixx had a reasonable scientific basis for saying that Zicam did not cause anosmia.

Less than a month later, however, Matrixx conceded that "insufficient scientific evidence [exists] at this time to determine if zinc gluconate, when used as recommended, affects a person's ability to smell." JA82a (¶ 46).[28] Indeed, when Matrixx made those statements, Zicam was being marketed "without FDA approval," JA269a, and had not been subject to the FDA's testing and reporting requirements to determine whether it was "safe and effective in its proposed use(s), and whether [its] benefits . . . outweigh [its] risks."[29]

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[28] Matrixx argues (at 9 n.4) that this statement, in a February 27, 2004 8-K filing with the SEC, is irrelevant. On the contrary, the 8-K filing establishes that, as of February 19, 2004, Matrixx lacked any reasonable basis to say or imply that Zicam had been proved safe in the context of anosmia. Matrixx similarly lacked any such basis weeks earlier when it made its February 2 statements.

[29] FDA, *New Drug Application (NDA)*, http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDeveloped

2. Matrixx argues (*e.g.*, at 14, 46) that respondents were required to compare, in their complaint, the reports of anosmia known to Matrixx as of late 2003 with the total number of cases of anosmia in the relevant population.[30] No such requirement exists. Respondents were permitted to rely, especially for pleading purposes, on: the opinions of the doctors who reported the cases to Matrixx; the corroborating details in the reports (such as a burning sensation experienced in the nostrils); the background medical literature that strongly suggested zinc exposure could cause anosmia; and the comparative seriousness of the side effect – persistent lost sense of smell – with the affliction purportedly being mitigated, the common cold. Given those allegations, respondents' complaint satisfies the established totality-of-the-circumstances test for materiality.

Matrixx also argues (at, *e.g.*, 46-47) that respondents failed to exclude the possibility of a "co[n]-founding indicator," arguing that the complaint failed to "deny[] or contradict[]" the causal link between anosmia and infections caused by the common cold. But nothing in Rule 8, *Twombly*, or *Iqbal* suggests that a plaintiff bears the burden to anticipate and negate detailed factual counterarguments in a complaint. The issue of possible alternative causes for the reported incidences of Zicam-induced anosmia is

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andApproved/ApprovalApplications/NewDrugApplicationNDA/default.htm (last updated Aug. 20, 2010).

[30] Matrixx also argues (at 6 & n.1) that the number of reports was 12, rather than the 23 respondents stated in their opposition to certiorari, but states that "[t]he exact figure is irrelevant" for present purposes. Respondents agree with the latter point. The content and context of the information that Matrixx received are the key allegations here, not the precise number of individuals suffering from anosmia.

an evidentiary dispute that should be resolved on summary judgment or at trial, with the benefit of admissible expert opinion.

In any event, the doctors who linked Zicam to anosmia *had* considered, and rejected, the possibility that the subjects of their study were suffering from post-viral anosmia. *See supra* pp. 11-12. They did so because post-viral anosmia typically follows a severe cold, but study subjects typically had experienced mild colds. Further, subjects reported experiencing a burning pain in their nasal cavity followed immediately by persistent hyposmia or anosmia, which also is inconsistent with post-viral anosmia. *See id.*

C. The Complaint's Allegations Support A Strong Inference That Matrixx Acted With Scienter

1. "To establish liability under § 10(b) and Rule 10b-5, a private plaintiff must prove that the defendant acted with scienter, a mental state embracing intent to deceive, manipulate, or defraud." *Tellabs*, 551 U.S. at 319 (internal quotations omitted). Under the PSLRA, respondents must allege sufficient facts to establish "a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2). Sufficient facts are alleged where "a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *Tellabs*, 551 U.S. at 324.[31] "[T]he court's job is not to

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[31] All circuits to consider the issue have held that "a plaintiff may meet the scienter requirement by showing that the defendant acted intentionally or recklessly, though the Circuits differ on the degree of recklessness required." *Tellabs*, 551 U.S. at 319 n.3. Matrixx has not questioned that rule. The Court therefore should assume that respondents may prevail by show-

scrutinize each allegation in isolation but to assess all the allegations holistically." *Id.* at 326. Such scrutiny can reveal a strong inference of scienter despite the "absence of a motive allegation." *Id.* at 325.

2.a. The complaint alleges that, in September 2003, Matrixx attempted to stop Dr. Jafek from publishing his findings – or at least from using either "Matrixx" or "Zicam" in his presentation – through a baseless threat to sue him. JA61a (¶ 4) (asserting that "as a legal matter" Jafek did "not have [Matrixx's] permission to use their company name or product trademarks"); *see also* JA101a (¶ 64) (Dr. Jafek deleted references to Zicam or Matrixx from his poster presentation to avoid "threatened legal action from [Matrixx]").[32] When Dr. Jafek replied to Matrixx's initial letter seeking permission to use the names, Matrixx

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ing recklessness. In any event, respondents' allegations establish a strong inference even of purposeful deception.

[32] Matrixx lacked any reasonable basis for its claim that, "as a legal matter," Dr. Jafek needed permission to use "the company name or product trademarks," JA118a, in a presentation at a medical conference. A trademark owner has no right to silence criticism of its products that has no conceivable likelihood of "caus[ing] confusion" about the maker of any goods or services. 15 U.S.C. §§ 1114(1)(a), 1125(a)(1)(A); *see also, e.g.*, *Utah Lighthouse Ministry v. Foundation for Apologetic Info. & Research*, 527 F.3d 1045, 1052 (10th Cir. 2008) ("The Lanham Act is intended 'to protect the ability of consumers to distinguish among competing producers,' not to prevent all unauthorized uses.") (citation omitted). Matrixx also could not legitimately threaten Dr. Jafek with an action for disparagement or dilution of its trademarks because his speech was plainly noncommercial. *See* 15 U.S.C. § 1125(a)(1)(B) (disparagement action requires use of mark in "commercial advertising or promotion"); *see id.* § 1125(c)(3)(C) (dilution action unavailable for "[a]ny noncommercial use of a mark").

sent another letter refusing to grant permission. JA70a (¶ 29).

Matrixx's actions support a strong inference that its senior officers were well aware of the potential risk that the doctors' findings posed to its products, but intended to respond to that risk not through inquiry and disclosure but instead through concealing information from the public (including Matrixx's investors) for as long as possible. By September 2003, Matrix not only knew of Dr. Jafek's own research and presentation, but also had received two earlier similar reports and had been informed of studies showing the harmful effects of zinc on the sense of smell. *See supra* pp. 9-10.

Matrixx says (at 6-7) that it "attempted to obtain more information about the user complaints reported by Linschoten and Jafek," implying that it responded to those complaints in good faith. The record will not bear that interpretation. Matrixx cites nothing that it did to obtain more information about Dr. Linschoten's patients in 2002 – it merely told her that it had retained a consultant and invited her to participate in animal studies it claimed an intent to conduct. The record does not show, and Matrixx does not say, at what point it *actually* conducted any animal studies. Indeed, Matrixx's statement to Dr. Linschoten about planned animal studies, coupled with a complete absence of any reference to those studies in its 2003 or 2004 public statements, strengthens the inference of scienter by showing that Matrixx knew it needed to do more to have a reasonable basis to make pronouncements about the safety of intranasal Zicam.

As for the "requests" that Matrixx describes in its letter to Dr. Jafek, the doctor rightly perceived

them as threatening legal action rather than seeking information in good faith.[33] In any event, the fact that Matrixx's Vice President and Director of Research and Development personally followed up on communications with Drs. Linschoten and Jafek merely underscores that Matrixx *did* consider their findings a real concern for its business, but nevertheless attempted to conceal those findings until public disclosures forced its hand.

b. Matrixx's February 2004 statements that the "safety" of intranasal Zicam had been "well established" by clinical trials and that contrary allegations were "completely unfounded and misleading" also support a strong inference of scienter. JA77a-78a (¶ 38), 81a-82a (¶ 44). Those statements on their face conveyed the false impression that intranasal Zicam had been tested in clinical trials to determine whether it caused anosmia, when – as Matrixx admitted only a few weeks later – it had no evidence to support those statements. *See supra* pp. 15-16.

The timing of Matrixx's vigorous denials, followed by its reluctant admissions, supports a strong inference that Matrixx knew it lacked a reasonable basis for statements it made during the October 2003-February 2004 period. Did Matrixx have evidence of Zicam's safety in early February 2004 that somehow vanished in the following two weeks? Did the results

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[33] The letter asked Dr. Jafek to explain his "basis for linking [reports of anosmia] with the use of zinc nasal products" and specified that he should do so "*[p]rior* to [his] presentation next week." JA118a (emphasis added). It cautioned him "not to proceed with a program that does not accurately and fairly portray our company or our products." *Id.* Matrixx thus threatened a defamation suit without expressing genuine interest in learning more from Dr. Jafek.

of the earlier trials it had claimed "established" Zicam's safety change during that time? The inference that Matrixx intended to deceive (or at least spoke recklessly) is more "cogent," *Tellabs*, 551 U.S. at 314, than either of those unlikely scenarios.

3. Matrixx's only argument with respect to scienter is that the "most obvious inference" from the complaint is that "petitioners believed [the reports of Zicam-induced anosmia] were far too few, and too caught up with the confounding cold indicator, to indicate anything meaningful about adverse reactions to use of Zicam." Br. 49. Matrixx makes no attempt to address the information it actually possessed, the timing of its statement, or other facts that support a strong inference of scienter here. As with its materiality argument, Matrixx's argument on scienter thus rises or falls with its request for a bright-line rule requiring allegations of statistical significance before any statement about adverse drug effects can violate Rule 10b-5.

II. THIS COURT SHOULD REJECT MATRIXX'S PROPOSED BRIGHT-LINE RULE

Matrixx seeks a rule that a drug manufacturer has no duty to disclose to its investors information tending to show that its products cause adverse effects unless that information rises to the level of statistical significance. Such a rule would be unprecedented and unwise, and would rest on fundamental misunderstandings about the nature and meaning of the concept of statistical significance.

A. Statistical Significance Is Not The Same As Practical Importance

Researchers use the term "statistical significance" to characterize a result from a test that satisfies a particular kind of test designed to show that the

result is unlikely to have occurred by random chance. *See* David H. Kaye & David A. Freedman, *Reference Guide on Statistics, in Reference Manual on Scientific Evidence* 83, 122 (Fed. Judicial Ctr., 2d ed. 2000) ("*Reference Manual*"). The purpose of significance testing in this context is to assess whether two events (here, taking Zicam and developing anosmia) occur together often enough to make it sufficiently implausible that no actual underlying relationship exists between them.

To test for significance, the researcher typically develops a "null hypothesis" – *e.g.*, that there is *no* relationship between using intranasal Zicam and the onset of burning pain and subsequent anosmia. The researcher then selects a threshold (the "significance level") that reflects an acceptably low probability of rejecting a true null hypothesis – *e.g.*, of concluding that a relationship between Zicam and anosmia exists based on observations that in fact reflect random chance. In theory, the significance level the researcher chooses should reflect "contextual considerations" about the particular purpose of the experiment and requires a balancing of the costs of different possible errors: the error of finding a relationship where there is none (a "Type I" error) as opposed to the error of overlooking a relationship where one exists (a "Type II" error). *See* Kenneth J. Rothman et al., *Modern Epidemiology* 153, 155 (3d ed. 2008). In practice, however, significance levels of 0.1 (10%), 0.05 (5%), and 0.01 (1%) often are used in academic and industry research as rules of thumb without any explicit consideration of error costs.

The researcher then calculates a value (referred to as *p*) that reflects the probability that the observed data could have occurred *even if* the null hypothesis

were in fact true. If the *p*-value falls below the pre-selected significance level, the researcher finds a statistically significant result and rejects the null hypothesis. *See id.* at 153. A *p*-value that *exceeds* the significance level, however, does not necessarily lead the researcher to *accept* the null hypothesis; rather, the researcher concludes only that the null hypothesis "cannot [be] reject[ed]." *Id.* at 151-52.

Moreover, as Matrixx concedes (at 35 n.16), neither the *p*-value itself nor a finding of statistical significance at any particular level determines whether a result is practically important. Significance levels and *p*-values do not incorporate either the *magnitude* or the *implications* of a study's result. For example, researchers studying a drug that cures cancer might estimate that 5% of those taking the drug will experience temporary nausea and might find that result statistically significant at the 0.01 level. But regulators, doctors, and patients would view such a finding as a minimal consideration given the drug's great benefits.

By the same token, a causal relationship of potentially great practical importance may not necessarily produce findings that reach the level of statistical significance. For example, researchers studying an anti-nausea drug might estimate that those taking the drug would have a one-third increase in their risk of developing cancer as a result, but might calculate a *p*-value of 0.07 or 0.12 and so not find that result significant at the 0.05 level. Based on such results, researchers would not formally reject a null hypothesis that taking the drug was unrelated to cancer. But doctors likely would not prescribe the drug and patients likely would refuse to take it. The

estimated risk, although uncertain, would be too great relative to the drug's benefits.

B. Adopting Statistical Significance As A Bright-Line Rule For Materiality Would Depart From Well-Settled Precedent

1. In *Basic*, this Court declined to adopt a "usable, bright-line rule" defining information about preliminary merger discussions as immaterial "until 'agreement-in-principle' as to the price and structure of the transaction ha[d] been reached between the would-be merger partners." 485 U.S. at 232-33. The Court's reasons apply here with equal force.

a. *Basic* explained that "[a]ny approach that designates a single fact or occurrence as always determinative of an inherently fact-specific finding such as materiality, must necessarily be overinclusive or underinclusive." *Id.* at 236.[34] That general observation holds true here: requiring a statistical-significance finding as categorically necessary before information about adverse drug effects is deemed material would be underinclusive, authorizing drug companies to conceal information that reasonable investors would consider important.

Matrixx's attempt to reconcile its rule with *Basic* rests on its erroneous assertion that "the statistical significance standard *defines* the information a reasonable investor would consider relevant." Br. 43. In appropriate cases, a reasonable investor would

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[34] The SEC has followed the same approach in administrative guidance. *See* SEC, Staff Accounting Bulletin No. 99, at 3 (1999) (quoting with approval the position of the Financial Accounting Standards Board that "no general standards of materiality could be formulated to take into account all the considerations that enter into an experienced human judgment"), *available at* http://www.sec.gov/interps/account/sab99.htm.

consider relevant both non-statistical information, such as diagnoses by treating physicians, without the need for statistical support; and statistical information suggesting a causal link without finding statistical significance. *See infra* pp. 47-53.

b. *Basic* also explained that the materiality requirement "filter[s] out essentially useless information that a reasonable investor would not consider significant, even as part of a larger 'mix' of factors to consider." 485 U.S. at 234. That standard has no room for "paternalistic withholding of accurate information" on the ground that investors will act imprudently if they receive it. *Id.*

Matrixx relies upon the types of arguments this Court rejected in *Basic*. For example, Matrixx contends (at 30) that "[i]nvestors generally are not scientists or epidemiologists and cannot be expected to sift significant from insignificant scientific data with ease" and that "disclosure of [adverse event reports about drugs] can mislead investors into undervaluing or prematurely selling a security." Matrixx's paternalistic position is that information should be deemed immaterial not because investors will ignore it, but because investors will *use* it incorrectly and make decisions against their own best interests.

Matrixx also relies heavily (at 3, 30, and 44) on this Court's statement in *TSC* that the materiality standard should not be set so low as to "bury the shareholders in an avalanche of trivial information." 426 U.S. at 448. The *TSC* Court expressed that concern as a reason supporting its "total mix" standard for materiality. When a substantial likelihood exists that a reasonable investor would view information as reasonably altering the total mix of available information, the information is not "trivial" under *TSC*.

No purported concern for overburdening investors justifies withholding it.

Matrixx also inaccurately portrays how the nationwide securities markets assimilate information about public companies. The market's capacity to use information is not limited to an individual lay investor's abilities. *Cf. Flamm v. Eberstadt*, 814 F.2d 1169, 1175 (7th Cir. 1987) ("Disclosures to the market as a whole cannot be limited to what is fit for rubes."). Legions of professional securities analysts and investment advisors make their livelihoods by analyzing massive volumes of information about public companies.

Those professionals can understand nuanced statistical information or obtain expert assistance to assess it. Their analyses affect decisions by their customers and clients, and ultimately affect stock prices. *See Dirks v. SEC*, 463 U.S. 646, 658-59 (1983) (observing that, in a "healthy market," securities analysts "ferret out and analyze information" to obtain a "basis for judgments as to the market worth of a corporation's securities") (internal quotations omitted). That process will not function properly if issuers withhold useful information because lay investors might misinterpret it.

c. *Basic* also admonished that administrative convenience and the "comfort of corporate managers" do not justify depriving investors, analysts, and advisors of material information. 485 U.S. at 236. That part of *Basic*'s holding forecloses Matrixx's argument (at 28) that its bright-line rule is necessary to ensure that corporate managers do not "inoculate themselves against . . . securities-fraud suits" through excessive disclosures. "[T]he Securities Acts and Congress' policy decisions" place on every issuer of

securities a duty to "exercise [its] judgment in the light of all the circumstances" when determining whether to disclose information. *Basic*, 485 U.S. at 236. An issuer genuinely attempting to comply with that duty can rely on the PSLRA (which does not include any heightened materiality standard) to protect it from "frivolous, lawyer-driven litigation." *Tellabs*, 551 U.S. at 322.

2. Matrixx asserts that court of appeals decisions hold that "§ 10(b) plaintiffs must at least plead facts establishing that the rate of reported adverse incidents among product users exceeded the relevant background rate by a statistically significant degree." Br. 33 (citing *In re Carter-Wallace, Inc. Sec. Litig.*, 150 F.3d 153, 157 (2d Cir. 1998) ("*Carter-Wallace I*"), and *Oran v. Stafford*, 226 F.3d 275, 284 (3d Cir. 2000) (Alito, J.)). Matrixx overstates the holdings of those cases.

Both *Carter-Wallace I* and *Oran* state generally that drug companies "need not disclose isolated reports of illnesses suffered by users of their drugs until those reports provide statistically significant evidence that the ill effects may be caused by . . . use of the drugs." *Carter-Wallace I*, 150 F.3d at 157; *accord Oran*, 226 F.3d at 284. Neither court considered the potential importance of non-statistical information about a drug's effects, such as case studies or clinical opinions formed by physicians, or even mentioned the possibility that such evidence might exist. Matrixx overreads those cases as rejecting the materiality of such evidence.

3.a. Matrixx also relies upon a string of cases (at 35-42) giving weight to statistical significance in products liability, employment discrimination, and other contexts. Those decisions do not help Matrixx,

because every one was rendered at the evidentiary stages of a case, not on the pleadings.

That difference in posture matters. A court weighing evidence (or ruling on its sufficiency or admissibility) may well consider the presence or absence of a finding of statistical significance. What Matrixx seeks is a rule prohibiting a court from permitting the gathering and presentation of evidence unless a finding of statistical significance is first alleged. The Federal Rules "do[] not impose a probability requirement at the pleading stage." *Twombly*, 550 U.S. at 556; *accord Iqbal*, 129 S. Ct. at 1949. Statistical significance is not just a probability requirement, but a very demanding one designed for "scientists search[ing] for certainty," rather than a "trier of fact" determining what is "more likely than not." *Pitre v. Western Elec. Co.*, 843 F.2d 1262, 1269 (10th Cir. 1988).

Castaneda v. Partida, 430 U.S. 482 (1977), and *Hazelwood School District v. United States*, 433 U.S. 299 (1977), on which Matrixx relies (at 35, 39, 41), illustrate *evidentiary* uses of statistical calculations. In *Castaneda*, the Court held that an underrepresentation of a protected class on Texas grand juries that would occur by chance less than 1 time in 10^{140} could establish a *prima facie* case of discrimination. *See* 430 U.S. at 496 n.17. In *Hazelwood*, the Court stated that, depending on its size, a much smaller discrepancy in school-teacher hiring might either support or undermine a case of discrimination. *See* 433 U.S. at 311-12. Neither case held or implied that the absence of a statistically significant underrepresentation would "necessarily exclude discriminatory design as the cause." *Craik v. Minnesota State Univ.*

Bd., 731 F.2d 465, 476 n.13 (8th Cir. 1984) (internal quotations omitted).

b. Further, Matrixx's cases are inapposite because they deal with the role of statistical significance in proving an actual casual link – for example, between a product and an injury, or a plaintiff's race and an adverse employment action. An investor alleging fraudulent misrepresentations or omissions does not need to show that a pharmaceutical manufacturer withheld information that would demonstrate by preponderant evidence that a drug actually had the harmful effects in question. Rather, "[p]robabilities determine the value of stock." *Pommer v. Medtest Corp.*, 961 F.2d 620, 623 (7th Cir. 1992) (Easterbrook, J.). A company's deliberate concealment of information about the probability that a drug will be found to cause harmful effects can be securities fraud if a reasonable investor would regard the probability itself as important, even if the drug remains more likely safe than not.

In this case, Matrixx concealed information showing a heightened risk that the public, the FDA, or the courts ultimately would conclude that intranasal Zicam products caused anosmia. Later, the risk was disclosed to the public and Matrixx's share value dropped. Still later, the risk came to fruition when the FDA concluded that Zicam was misbranded, and Matrixx removed the intranasal Zicam products from the market. A reasonable investor would have been concerned about the risk when Matrixx concealed it – just as Matrixx's actual investors were.

C. A Reasonable Investor Would Not Consider A Finding Of Statistical Significance A Prerequisite To Evaluating Otherwise Useful Information

This case turns on whether (as Matrixx and its *amici* contend) a reasonable investor would disregard any information about a potential problem with a drug except for a statistically significant result. A reasonable investor would not act that way.

1. Information suggesting that a drug might have a yet-unproven adverse effect is information about a "contingent or speculative" future event, *Basic*, 485 U.S. at 238, such as whether the drug subsequently may be the subject of litigation, regulatory action, or consumer disfavor. Assessing the materiality of contingent events requires "'balancing of both the indicated probability that the event will occur and the anticipated magnitude of the event in light of the totality of the company activity.'" *Id.* (quoting *SEC v. Texas Gulf Sulphur Co.*, 401 F.2d 833, 849 (2d Cir. 1968)).

In assessing the risk of a particular drug causing an important adverse effect, a reasonable investor would consider a broad range of different kinds of information. That range would include not only quantitative information about the number of adverse effects reported, but also, among other things, available background scientific and clinical information indicating that a potential problem was biologically plausible or implausible; case reports suggesting the existence of a problem with sufficient detail to be informative; and the opinions of researchers and treating physicians who have studied the drug's effects.

Even with regard to quantitative information, a reasonable investor would not wholly disregard information about the incidence of an adverse effect solely because the information did not incorporate a finding of statistical significance. If information is uncertain but potentially important, investors taking "calculated risks," *Texas Gulf Sulphur*, 401 F.2d at 849 n.10 (internal quotations omitted), will discount it, not discard it. Small changes to the estimated probability that a drug has a serious adverse effect can be important to investors if that drug (as here) provides a significant portion of the company's revenues and if that adverse effect would drastically undermine the drug's value.

2. Matrixx's arguments rest ultimately on a premise that only statistical significance should ever count as evidence of causation in the drug context. Matrixx argues that a complaint failing to "plead facts establishing that [adverse event reports] reflect a statistically significant correlation between use of [a] product and [a] reported adverse event" has "do[ne] *nothing* to show that the [reports] reflect a potentially causal relationship." Br. 42-43 (emphasis added). *Amicus* BayBio makes the same claim: that "[o]nly if a statistically significant connection between use of [a] drug and [an] adverse event is established is there *any meaning* from the incidence of the adverse event." Br. 5 (emphasis added). These claims are incorrect: many types of information other than statistical significance can alert a reasonable investor to a risk that more than "a chance sequence of events," Pet. Br. 25, has led to a cluster of reported problems with a drug.

a. Matrixx essentially ignores the relevance of *non-statistical* information, including clinical reason-

ing.[35] "For the treating physician, '[c]linical reasoning is the essential function of the physician.'" Mary Sue Henifin et al., *Reference Guide on Medical Testimony, in Reference Manual* 439, 461 (quoting Jerome P. Kassirer & Richard I. Kopelman, *Learning Clinical Reasoning* 2 (1991)) (alteration in original); *see also* Fed. R. Evid. 703 note (giving the "diagnosis" of a "treating physician" as a paradigmatic combination of expert opinion and first-hand observation). Where specialist researchers conclude that a drug causes serious adverse effects, their views are important information likely to affect decisions made by courts, regulators, and consumers – and, therefore, investors.

Courts have recognized that a physician's differential diagnosis (which identifies a likely cause of certain symptoms after ruling out other possibilities) can be reliable evidence of causation. *See, e.g., Turner v. Iowa Fire Equip. Co.*, 229 F.3d 1202, 1208

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[35] Matrixx concedes (at 44-45 n.22) that courts in numerous cases have "permit[ted] an inference of causation on the basis of scientifically reliable evidence other than statistically significant epidemiological data," but claims that "[t]his case does not present th[at] question" because respondents did not argue it in their brief in opposition. On the contrary, respondents argued that "[p]etitioners mischaracterize th[is] lawsuit as one primarily involving so-called 'adverse event reports'" when, in fact, it involved much more detailed and corroborated information, including "complaints . . . concern[ing] a singular, dramatic reaction – the user's loss of sense of smell following Zicam's application into the nose – that complainants and medical researchers each attributed specifically to Zicam." Br. in Opp. 17-18; *see also id.* at 16 (arguing that petitioners withheld from investors "specific information" that they received through "a variety of channels: otolaryngology researchers, consumer complaints, and personal-injury lawsuits"); *id.* at 2-5 (setting forth the relevant medical evidence in detail).

(8th Cir. 2000) ("[D]ifferential diagnosis is a tested methodology, has been subjected to peer review/publication, does not frequently lead to incorrect results, and is generally accepted in the medical community."); *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 263 (4th Cir. 1999) ("[A] reliable differential diagnosis provides a valid foundation for an expert opinion."); *Baker v. Dalkon Shield Claimants Trust*, 156 F.3d 248, 252-53 (1st Cir. 1998) (describing differential diagnosis as a "standard scientific technique, widely used in medicine").[36]

Even at the evidentiary phase, courts also have rejected the argument that only statistical significance can be reliable evidence of causation. *See, e.g., Westberry*, 178 F.3d at 262 (refusing to require "epidemiological studies" before admitting a doctor's causation opinion); *Heller v. Shaw Indus., Inc.*, 167 F.3d 146, 158 (3d Cir. 1999) ("[A] physician's diagnosis, based in part on a strong temporal relationship between symptoms and exposure, need not necessarily be supported by 'a statistically significant correlation.'"); *Ferebee v. Chevron Chem. Co.*, 736 F.2d 1529, 1536 (D.C. Cir. 1984) ("products liability law does not preclude recovery until a 'statistically significant' number of people have been injured").

b. Matrixx and BayBio also advance an erroneous view of statistical information. There is no difference in the *kind* of information conveyed by results of $p = 0.33$, $p = 0.1$, or $p = 0.05$, merely a difference in the degree of certainty. "[T]here is no sharp line between a 'significant' and a 'nonsignificant' difference; significance in statistics . . . varies continuously between extremes." Ralph L. Rosnow & Robert Rosenthal,

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[36] *See also* 4 *Weinstein's Federal Evidence* § 702.06[2][c][iii], at 702-131 & n.46 (2009 update) (collecting cases).

Statistical Procedures and the Justification of Knowledge in Psychological Science, 44 Am. Psychol. 1276, 1277 (1989). When human lives, or billions of dollars, turn on an uncertain question, a reasonable decision-maker would not stop considering information at the 0.05 level. As Judge Posner wrote in *Kadas v. MCI Systemhouse Corp.*, 255 F.3d 359 (7th Cir. 2001):

> The 5 percent test is arbitrary; it is influenced by the fact that scholarly publishers have limited space and don't want to clog up their journals and books with statistical findings that have a substantial probability of being a product of chance rather than of some interesting underlying relation between the variables of concern. Litigation generally is not fussy about evidence; much eyewitness and other nonquantitative evidence is subject to significant possibility of error, yet no effort is made to exclude it if it doesn't satisfy some counterpart to the 5 percent significance test.

Id. at 362-63.[37]

3. Scholars likewise recognize the overuse of statistical significance as an error:

> Statistical significance is . . . a diversion from the proper objects of scientific study. Significance, reduced to its narrow statistical meaning only, has little to do with a defensible notion of scientific inference, error analysis, or rational decision making. . . . Statistical significance should

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[37] *See also, e.g., MacDissi v. Valmont Indus., Inc.*, 856 F.2d 1054, 1058 n.3 (8th Cir. 1988) ("Even where quantitative evidence does not alone demonstrate discrimination to some judicially created standard of statistical conclusiveness, it is still relevant in conjunction with all other evidence in determining intentional discrimination.").

> be a tiny part of an inquiry concerned with the *size* and *importance* of relationships.

Stephen T. Ziliak & Deirdre N. McCloskey, *The Cult of Statistical Significance: How the Standard Error Costs Us Jobs, Justice, and Lives* 2 (2009) (emphasis added).

A long line of scholarly works agrees. The point has been made by statisticians,[38] epidemiologists,[39] medical researchers,[40] and researchers in other fields.[41] Indeed, in the seminal *Daubert* case, a group

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[38] *See, e.g.*, David A. Freedman, *Statistical Models: Theory and Practice* 70 (rev. ed. 2009) (describing "[s]tatistical significance" as "technical jargon" that has "acquired enormous – and richly undeserved – emotional power"); Frank Yates, *The Influence of* Statistical Methods for Research Workers *on the Development of the Science of Statistics*, 46 J. Am. Stat. Ass'n 19, 32 (1951) (criticizing researchers who give "undue attention to the results of . . . tests of significance . . . and too little to the estimates of . . . magnitude").

[39] *See, e.g.*, Rothman, *Modern Epidemiology* at 163 ("[B]ecause statistical hypothesis testing promotes so much misinterpretation, we recommend avoiding its use in epidemiologic presentations and research reports.").

[40] *See, e.g.*, Jonathan A C Sterne & George Davey Smith, *Sifting the Evidence – What's Wrong with Significance Tests?*, 322 British Med. J. 226, 226 (2001) (recommending that the "[r]esults of medical research should not be reported as 'significant' or 'non-significant'"); David A. Savitz, *Is Statistical Significance Testing Useful in Interpreting Data?* 7 Reproductive Toxicology 95, 96 (1993) ("[S]tatistical significance testing is not useful in the analysis or interpretation of scientific research.").

[41] *See, e.g.*, Larry G. Daniel, *Statistical Significance Testing: A Historical Overview of Misuse and Misinterpretation with Implications for the Editorial Policies of Educational Journals*, 5 Research in the Schools 23, 23-24 (1998) (collecting criticisms of the misuse of statistical significance tests in the field of education research); William W. Rozeboom, *The Fallacy of the Null-Hypothesis Significance Test*, 57 Psychol. Bull. 416, 416-17

of respected epidemiologists warned this Court that, "[w]hen used to evaluate the association between exposure and disease, the concept of statistical significance is often misleading and never descriptive of the magnitude of effect or the precision of measurement" and that a factfinder is misled when "told that a body of data is not 'statistically significant' [and so] made to believe that the data has no value."[42]

4.a. Matrixx's proposed rule has other defects as well. As proposed, the rule would not even draw a bright line. It is impossible to say whether information is statistically significant without pre-selecting a particular critical value for significance. *See supra* pp. 39-40. Matrixx hints (at 35-36) that the Court might adopt a threshold of $p < 0.05$, but ultimately argues only that the level must be "meaningful." With no pre-selected threshold, a statistical significance requirement would not allow companies to determine whether information was material. And to the extent this Court were to accept Matrixx's suggestion and impose a specific threshold, it would be adopting on purely policy grounds an arbitrary statistical threshold far outside its expertise.

Matrixx even suggests in a footnote that statistical significance may not always be required, correctly recognizing that courts have held other forms of evidence to be "scientifically reliable." Br. 44-45 n.22 (citing cases relying on non-statistical evidence, but claiming the argument was waived here); *but see supra* note 35 (rebutting Matrixx's waiver argument).

(1960) (describing the "'null-hypothesis significance test'" as "seldom if ever appropriate to the aims of scientific research").

[42] Brief *Amici Curiae* of Professors Kenneth Rothman et al. at 4, *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993) (No. 92-102), 1992 WL 12006438.

So do several of its *amici*.[43] That suggestion further undermines not only the alleged certainty Matrixx seeks, but also (by turning this case into fact-specific error correction) the basis on which this Court granted review.

b. Matrixx's proposed rule also would decrease "investors' ability to recover on meritorious claims." *Tellabs*, 551 U.S. at 322. Establishing a statistically significant result usually requires expert testimony from an epidemiologist, econometrician, or statistician, based on a developed factual record. Even if investors retained experts for pre-filing investigation (itself a significant and unjustified burden), any pre-filing analysis could well be inconclusive for lack of access to information controlled by defendants. Here, for example, the Warning Letter states that "Matrixx appears to have more than 800 reports related to loss of sense of smell associated with Zicam Cold Remedy intranasal products" that it never sent to the FDA. JA272a. Respondents have no access to those reports and do not know how many describe incidents before February 2004.

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[43] *See* Consumer Healthcare Products Ass'n et al. *Amicus* Br. 21 (equating "statistical significance" with "sufficient evidence, based on appropriate analysis and other pertinent information, of a causal association"); DRI *Amicus* Br. 33 n.8 (suggesting that the standard include whether reports have been "medically or scientifically substantiated" and whether a company's management has "reached an internal consensus"); PhRMA/BIO *Amicus* Br. 22 ("in certain limited circumstances, statistically insignificant adverse event reports may arise together with *other* information that, when viewed as a whole, establishes that drug sales are threatened").

D. Adverse Events Reports Do Not Require Special Treatment In The Materiality Analysis

Matrixx extensively discusses (at 17-32) adverse event reports, which drug manufacturers provide to the FDA under 21 U.S.C. § 379aa and 21 C.F.R. § 314.80. Much of Matrixx's brief (like those of most of its *amici*) argues that adverse event reports, taken as a class, are not reliable evidence of causation. That argument is a red herring.

1. This case does not even involve adverse event reports in the regulatory sense. No mandatory reporting requirement applied to Zicam in 2003 or 2004. *See supra* pp. 8-9. Instead, this case involves voluntary, unregulated communications from knowledgeable specialists who considered it important to warn Matrixx and their professional colleagues about the effects of Zicam. Matrixx's arguments (at 19-20) about regulatory adverse event reports that must be filed "whether or not [the event is] considered drug related," 21 C.F.R. § 314.80(a), lack any relation to the facts alleged in the complaint. The Ninth Circuit did not hold, and respondents have never argued, that all adverse event reports are material. Respondents were required only to allege plausibly that the particular information at issue in this case was material.

2. Further, Matrixx's arguments about the low probative value of adverse event reports generally do not justify treating all adverse event reports as lacking useful information.[44] "Context matters." *Burlington*, 548 U.S. at 69. Whether the reports

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[44] Matrixx's argument (at 23-24) that such reports are hearsay is irrelevant because the question here is what investors regard as material, not what is admissible evidence at trial.

come from respected clinicians or individual patients, identify serious or trivial side effects, reflect a plausible biological causal relationship, or are corroborated by other information available to an issuer are all relevant to materiality. Indeed, Matrixx itself defines (at 17) "AERs" (*i.e.*, adverse event reports) to include "direct complaints by users to manufacturers, reports by doctors about reported or observed patient reactions, more detailed case reports published by doctors in medical journals, or larger scale published clinical studies." It never explains why the differences among those types of information do not matter for materiality.

Matrixx also lists in the addendum to its brief a number of cases ruling that adverse event reports, or case reports more generally, are unreliable evidence of causation. As with Matrixx's cases on the evidentiary weight to be given statistical significance, *see supra* pp. 44-46, those cases have little import here because they were all decided at the evidentiary stages of the case, rather than on the pleadings, and all addressed what was needed for actual causation, rather than to plead materiality to investors.

3. Matrixx argues (at 29, 44) that the difficulty of making case-by-case determinations about information concerning adverse drug effects is so great that, without a bright-line rule, "companies would have a strong incentive simply to disclose all the AERs they receive." That concern is exaggerated, because corporate managers have a stronger incentive to manage public perceptions of their company. Most pursue that goal through appropriate judgments about which risks are material, often with the aid of counsel.

Matrixx also warns (at 30) that "[e]xcessive disclosure" of adverse event reports will confuse the market. The concern is an odd one – as Matrixx's *amici* PhRMA and BIO acknowledge (at 16), "most adverse event data are already made available to the public by the FDA."[45] If that raw information could somehow impair the functioning of the market, it already would be doing so. The information at issue in *this* case, of course, was not subject to mandatory reporting and publication. *See supra* pp. 8-9.

4. Matrixx challenges respondents to say (at 48-49) whether "20," or "18," or "12," or "11, or seven, or four" adverse event reports, "[o]r just one," would be material, arguing that a bright-line rule based on statistical significance is the only solution. That challenge misunderstands a totality-of-the-circumstances test. "[A] tyro thinks to puzzle you by asking you where you are going to draw the line . . . . But the theory of the law is that such lines exist." Oliver Wendell Holmes, *Law in Science and Science in Law*, 12 Harv. L. Rev. 443, 457 (1899). Under *Basic*, the correct answer is that it depends upon the nature of the reports and other relevant facts. A hundred unverified reports of a headache accompanying drug use might not be material. Ten well-documented reports of a deadly illness could well be: six reports of death from the rare condition aplastic anemia were deemed immaterial in *Carter-Wallace I*, but 10 were enough to take the drug in that case off the market. *See* 150 F.3d at 155.

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[45] *See* FDA, *The Adverse Event Reporting System (AERS): Latest Quarterly Data Files*, http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm082193.htm.

The line-drawing problem is far more troublesome for Matrixx's theory, because Matrixx seeks to ignore facts that should make a difference. Suppose 10 patients had reported an important adverse side effect for a drug – but each had been examined by a different, well-reputed specialist, and all 10 doctors had concluded independently that the drug caused the problem. Matrixx's attempt to "confin[e] materiality to a rigid formula," *Basic*, 485 U.S. at 236, would prevent courts from even considering allegations about such expert conclusions – contrary to precedent, actual investor behavior, and common sense.

CONCLUSION

The judgment of the court of appeals should be affirmed.

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REPLY BRIEF

No. 09-1156

IN THE

Supreme Court of the United States

MATRIXX INITIATIVES, INC., ET AL.,
Petitioners,

v.

JAMES SIRACUSANO AND NECA-IBEW PENSION FUND,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

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REPLY BRIEF FOR PETITIONERS

It should hardly be controversial that uncorroborated, anecdotal hearsay reports of adverse health events following use of a popular non-prescription drug product do not themselves tell a reasonable investor anything useful about whether to invest in the drug company. But respondents and their amici insist that all such reports—even *one* such report—must be disclosed to investors, because *any* information that "simply suggest[s]" a possible link between a drug and some adverse effect is information *someone* might act on, and thus is information an investor would want to have. U.S. Br. 8.

That argument fundamentally misconceives the materiality standard. It is not a "day trader looking for an edge" standard, requiring companies to disclose anything simply because *some* investors want to know everything. According to the Solicitor General, an investor might even want to know about misleading, unreliable, or even outright false information about a company's product because such information could affect the conduct of ill-informed or irrational consumers and other actors. Human behavior certainly can be driven by rumor and innuendo, as anyone with an e-mail account knows. But materiality under the securities laws has never been based on what ignorant or paranoid people might do with unreliable or inaccurate information. Materiality turns instead on the significance of accurate, reliable information to a *hypothetical, reasonable* investor.

In this case, the handful of adverse event reports ("AERs") Matrixx Initiatives, Inc. ("Matrixx") alleg-

edly received before February 6, 2004—12-23 uncorroborated hearsay reports, over a four-year period, out of millions of units sold—did not convey any reliable information about whether Matrixx's product Zicam was causally connected to the reported event, anosmia. If Matrixx was required to disclose those few reports as material information, then materiality has no objective meaning at all, and companies will have no intelligible standard to guide their disclosure determinations. Nor can the mere existence of such reports suffice to establish that petitioners acted with the requisite scienter, i.e., that they knew they were withholding information they were required to disclose.

Respondents defended their complaint below, and in opposing certiorari, on the ground that the few AERs they identified in their complaint were, *in and of themselves*, material information that petitioners knew they were required to disclose to investors. Respondents repeat that flawed argument here, but they also try a different tack, essentially rewriting their complaint to cite various *additional* facts about Zicam that they now say suffice to establish an inference of anosmia causation reliable enough that it should have been disclosed. That argument fails as well: not only are respondents constrained by the allegations they pled, but the facts they now add—most prominently, a 1982 study of the "olfactory mucosa of catfish" (RB7)—still fail to establish any reliable basis for inferring a causal relationship that petitioners should have disclosed.

I. RESPONDENTS' COMPLAINT FAILS TO PLEAD FACTS ESTABLISHING THAT PETITIONERS OMITTED MATERIAL INFORMATION ABOUT ZICAM

Respondents and their amici advance essentially four reasons the complaint adequately pleads materiality:

- Materiality under *Basic Inc. v. Levinson*, 485 U.S. 224 (1988), is a fact-intensive element that cannot be determined at the pleading stage.
- "Practical importance," rather than statistical significance, should be the standard for determining when AERs must be disclosed.
- Investors care about virtually any information concerning a product, not just scientifically reliable information.
- There is evidence in addition to the AERs establishing a causal link between Zicam and anosmia.

Those arguments are meritless.

A. Materiality Is Routinely Adjudicated At The Pleading Stage When The Facts Alleged Are Legally Insufficient

Respondents contend that because materiality is a "totality of the circumstances" inquiry, it is unsuitable for adjudication at the pleading stage. RB25-26; *see* U.S. Br. 28. Respondents also argue that dismissal of their complaint would require adoption of an impermissible "bright line rule." RB41, 54. Neither contention is correct.

1. As a general matter, while materiality in all fraud contexts is a factual matter, "[n]o shortage of cases ... make clear that materiality may be resolved by a court as a matter of law." *Greenhouse v. MCG Capital Corp.*, 392 F.3d 650, 657 (4th Cir. 2004); *see, e.g., Shandong Yinguang Chem. Indus. Joint Stock Co. v. Potter*, 607 F.3d 1029, 1033 (5th Cir. 2010); *ECA & Local 134 IBEW Joint Pension Trust of Chi. v. JP Morgan Chase Co.*, 553 F.3d 187, 205-06 (2d Cir. 2009); *U.S. ex rel. Wilson v. Kellogg Brown & Root, Inc.*, 525 F.3d 370, 376, 378 (4th Cir. 2008); *U.S. ex rel. Marcy v. Rowan Cos.*, 520 F.3d 384, 389-90 (5th Cir. 2008); *Newcal Indus., Inc. v. Ikon Office Solution*, 513 F.3d 1038, 1053 (9th Cir. 2008); *In re AMDOCS Ltd. Sec. Litig.*, 390 F.3d 542, 548 (8th Cir. 2004); *Kapps v. Torch Offshore, Inc.*, 379 F.3d 207, 216 (5th Cir. 2004). If the facts alleged, found to be true by the factfinder, would not suffice to permit a legally sustainable finding of materiality, then the complaint must be dismissed. *See Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949-50 (2009).

Respondents thus cannot salvage their complaint by pointing to its pleading-stage status. The complaint fails as a matter of law because it does not identify information upon which a reasonable investor would rely in making investment decisions.

2. Nor does *Basic* prohibit courts from treating raw AERs as generally immaterial absent statistical significance. Courts applying *Basic* have not hesitated to identify categories of information considered immaterial as a matter of law. *See* SIFMA/Chamber Br. 14. The *Basic* Court rejected the bright-line rule proposed *in that case*—not *all* rules or intelligible standards. The rule in *Basic* would have determined

the materiality of information about potential mergers according to the artificial and subjective question—easily manipulated after the fact— whether an "agreement in principle" had been reached. 485 U.S. at 233-36. By contrast, the standard of statistical significance is objective, cannot be manipulated by company executives, and represents an intelligible standard for determining when AERs provide material information.[1]

Matrixx does not seek "a bright-line rule requiring statistical significance for *any* allegation of a failure to disclose information about adverse drug effects to be material under the securities laws." RB21. The point is not that "facts about adverse drug effects are *per se* immaterial absent statistically significant data." U.S. Br. 25. It is, rather, that *AERs themselves* are unreliable indicators of a causal link between the drug and the reported effect, and thus *AERs themselves* are immaterial unless they reveal a statistically significant difference between the rate of reported incidents and the background rate for the relevant population. PB16, 42-44. It is true that *other* information can establish a

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[1] Noting that materiality applies both to omissions and misrepresentations, the Solicitor General suggests that applying a statistical-significance standard to AER data would permit a company to falsely deny the existence of "credible" information concerning adverse events "associated with use of its drug." U.S. Br. 24-25. Not so. If the company has knowledge of a "credible" basis for inferring that the drug is actually associated with the adverse event, then it cannot falsely deny the existence of that information. But uncorroborated, anecdotal incident reports are *not* a credible basis for inferring an association.

scientifically reliable inference of causation. PB 44 n.22; PhRMA/BIO Br. 22. But if securities-fraud plaintiffs want to pursue a case based on the proposition that a drug company withheld information meaningfully indicating a problem with a drug, they must plead all the facts necessary to establish that proposition. *See Iqbal*, 129 S. Ct. at 1949-50. This is not such a case, as explained below, *infra* at 12-22.

3. Respondents argue that a statistical-significance standard would diminish the prospect for recovery on valid claims by making it too difficult to plead a claim based on AERs. RB54. But as just explained, the procedural posture in this case is irrelevant: if a handful of AERs out of millions of products purchased would be legally insufficient to permit recovery, then alleging that number of AERs is insufficient at the pleading stage.

In any event, commissioning an epidemiological study (U.S. Br. 23) is not required at the pleading stage. For example, one can draw a reasonable inference about the number of users of a product from SEC filings. PB46. Medical treatises and articles typically will identify the background rate of a health condition. Although ethical issues may complicate randomized studies of adverse health effects (*see* Medical Researchers Br. 11), observational studies are a well-recognized alternative that can be performed using adverse event data. *See* Michael D. Green et al., Reference Guide on Epidemiology, *in* Federal Judicial Center, Reference Manual on Scientific Evidence ("FJC Manual") 339-45 (2d ed. 2000); BayBio Br. 13-14.

To be sure, in some situations the relative rarity of certain adverse effects and the difficulty of collecting large samples of AER data might make proper statistical-significance analysis "an exercise in futility." Statistics Experts Br. 19-21. But if AER data are insufficient to support a reliable inference of causation, it does not follow that plaintiffs should be allowed to plead materiality based on a handful of uncorroborated, anecdotal incident reports. It simply means that in some cases securities-fraud plaintiffs will need other information to make out a plausible claim that the company knowingly withheld reliable information that its product causes a serious adverse event. If plaintiffs cannot plead (on information and belief) facts necessary to establish that essential proposition, the correct response is to *dismiss their case*—not to find ways to permit them to proceed without an adequate factual basis.

B. "Practical Importance" Is Not A Substitute For Statistical Significance

Respondents suggest that "practical importance," rather than statistical significance, should govern materiality determinations. RB38-41; *see* U.S. Br. 13. The argument at least concedes that some objective standard is required, and that materiality is not the one-way disclosure ratchet respondents elsewhere describe it to be.

But practical importance is not a substitute for statistical significance. Indeed, statistical significance is *antecedent* to practical importance for epidemiological data: a study might provide statistically significant evidence that a drug increases the risk of an adverse event by only a practically trivial

amount, or the event might be minor compared to the drug's benefits (e.g., increased acne from an anti-cancer medication). *See* David H. Kaye & David A. Freedman, Reference Guide on Statistics, *in* FJC Manual 124. But a causal connection cannot be practically important if it does not even exist. The point of statistical-significance analysis is to separate potentially causal connections from the *post hoc ergo propter hoc* fallacy that often infects lay, anecdotal observations like those reported in raw AERs.

To illustrate practical importance, respondents hypothesize an anti-nausea drug that appears to increase the risk of cancer by 33%, but only at a p-value of .07 or .12, above the typical .05 or .10 thresholds for statistical significance. RB40; *see* U.S. Br. 14 (similar); *see also* Green et al., Reference Guide on Epidemiology, at 357-59. Respondents say that consumers and investors might nevertheless care given the seemingly enormous consequences. Notably, however, they illustrate their point using p-values close to typical (not required) thresholds of statistical significance. They could not seriously suggest that consumers or investors would be concerned if (to use analogous facts) 12-23 users out of millions reported they contracted cancer after using the anti-nausea medication, given the cancer rate in the general population.[2] Thus, while respondents'

[2] In general, no reasonable scientist would contend that numerical data significant at, for example, a .50 significance level reflect a meaningful possibility that the observed incidence rate was due to an actual correlation. That "would sanction the epidemiological equivalent of garbage." Michael D. Green, *Science Is to Law as the Burden of Proof is to Significance Testing*, 37 Jurimetrics 205, 221-22 (1997).

example may suggest that statistical significance *at .05 or .10 p-values* need not be talismanic in all circumstances (*see* PB35-36), it also confirms the point relevant here: *some* meaningful measure of statistical significance must be applied to determine whether uncorroborated, anecdotal, hearsay incident reports reflect anything more than background noise or confounding by indication.

C. The Materiality Standard Must Facilitate Filtering As Well As Disclosure

Respondents contend that statistical significance should not be required because actual investors rely on all kinds of different information. RB42-43. "Even reports that *simply suggest* causation" must be disclosed, says the Solicitor General, because they might "affect the behavior of consumers, potential litigants, and the FDA." U.S. Br. 8 (emphases added).

These arguments would turn materiality standards into a disclosure free-for-all. Respondents condemn as "paternalistic" (RB42) any role for courts in determining what a *reasonable* investor would deem useful. But the law must exclude *some* information, otherwise materiality has no meaning. Courts therefore must distinguish, in some way, information that would be useful to a reasonable investor from information that would be useful only to an unreasonable investor. Disdaining such line-drawing as paternalism simply avoids the issue.

It is doubtless true that some people could be affected by unverified, unreliable reports that "simply suggest" causation, without regard to their truth or accuracy. For years many consumers would not pur-

chase products from Procter & Gamble because of a ridiculous rumor that the company was Satanic. *See P&G Co. v. Amway Corp.*, 242 F.3d 539, 541 (5th Cir. 2001). But no decision of this Court bases securities-law disclosure obligations on how ignorant or paranoid people might react to unreliable or even false information. On that view materiality again would be a meaningless standard—companies would be required to disclose essentially everything, because it is impossible to *rationally* predict *irrational* reactions.

Because they object to the entire enterprise of drawing materiality lines, respondents largely ignore the critical "filtering" function of materiality that this Court has emphasized. *See Basic*, 485 U.S. at 234; *TSC Indus., Inc. v. Northway, Inc.*, 426 U.S. 438, 448-49 (1976); *Jackvony v. RIHT Fin. Corp.*, 873 F.2d 411, 415 (1st Cir. 1989) (Breyer, J.). Overdisclosure provoked by lax or insufficiently clear materiality standards is just as harmful to investors as underdisclosure. PB30-33. Respondents' observation that raw AER data are already available on the FDA's website (RB57; U.S. Br. 26) overlooks the signaling effect of information provided by the company itself. Investors plainly would assume that a company would report such information only if it established a reliable basis for concern—unless companies actually disclosed all AERs as routinely as the FDA does (U.S. Br. 26), in which case disclosure would be pointless. PB29-30. Moreover, respondents' approach would require manufacturers to disclose AERs for all products and all events, even those not governed by FDA requirements (as here), or serious

enough to trigger FDA-imposed reporting responsibilities. *See, e.g.*, 21 U.S.C. § 379aa(c)(1), (e).

Unlike respondents, the Solicitor General concedes that *Basic*'s materiality standard "would sometimes permit a company to withhold adverse drug information." U.S. Br. 29. But the proffered examples—"a single report of an adverse event from an anonymous user," or an event "minor and transient" in nature for a drug with only a trivial impact on company revenues (*id.*)—demonstrate the emptiness of the concession. So does the Solicitor General's position in this very case: if Matrixx was required to disclose to investors 12-23 unverified reports of anosmia out of millions of units sold over four years, among a population already uniquely susceptible to anosmia, then no company could confidently withhold limited, unreliable data without risking exposure to costly and time-consuming securities-fraud strike suits.

The Solicitor General's apparent concession to *Basic*'s "filtering" requirement thus comes to nothing, leaving the contrary proposition he otherwise urges: almost all information *could* matter to *someone*—whether it be professional investors who appreciate nuance, or irrational consumers who elevate rumor over data. That view even more clearly would compel companies to inundate shareholders with uncorroborated, misleading, even utterly false assertions about the company's products, "a result that is hardly conducive to informed decisionmaking." *TSC*, 426 U.S. at 448-49.

Properly conceived, the materiality requirement presupposes a hypothetical, reasonable investor who

wants *accurate* and *reliable* information about a company—not information that is "speculative," overly "contingent," or "unreliable." *In re Rockefeller Ctr. Props., Inc. Sec. Litig.*, 184 F.3d 280, 290 (3d Cir. 1999). "To hold otherwise would result in endless and bewildering guesses as to the need for disclosure ... and threaten to 'bury the shareholders in an avalanche of trivial information'; the very perils that the ... materiality requirement serves to avoid." *Taylor v. First Union Corp. of S.C.*, 857 F.2d 240, 245 (4th Cir. 1988) (quoting *TSC*, 426 U.S. at 448-49).

D. Respondents' Complaint Does Not Plead Other Facts Sufficient To Establish Materiality

The complaint's basic theory of securities fraud is that the raw number of anosmia-related AERs received by Matrixx as of February 6, 2004—a total of 12-23 over a four-year period—was material information. That theory is consistent with the arguments, discussed above, that companies must disclose any fact—even a *single* anecdotal report—that merely "suggests" a causal connection between a consumer product and an adverse event. While still defending that extraordinary theory, respondents also now advance a new fraud theory, which focuses on various asserted facts about Zicam, many not alleged in the complaint. Neither theory justifies reversal of the district court's order of dismissal.

1. The theory of securities fraud actually asserted in the complaint is that petitioners deliberately made material misstatements regarding Zicam that "failed to disclose ... numerous users of the Zi-

cam product" had complained of anosmia. *See* J.A. 73a (¶ 32); *see also* J.A. 67a (¶ 24); J.A. 79a (¶ 39(d)). The undisclosed numerical data was allegedly reported to petitioners by, among others, "researchers at the University of Colorado." J.A. 74a (¶ 33).

The district court framed the question as whether petitioners committed securities fraud when they did not inform the markets of "12 user complaints" and "the University of Colorado study." Pet. App. 50a. Given that the user complaints were not "statistically significant," and that respondents had "failed to allege that during the class period, Defendants were presented with any evidence that the University of Colorado study was reliable," the court held that the complaint failed to allege materiality adequately. *Id.*

On appeal to the Ninth Circuit, respondents confirmed that their complaint focused on the *number* of anosmia-related AERs Matrixx had received. The "correct analysis of materiality here," respondents argued, "asks ... *only* whether a reasonable shareholder would consider it important that *large numbers* of Zicam users had lost their sense of smell." Plaintiff-Appellants' C.A. Reply Br. at 3 (emphases added, quotation omitted). In opposing certiorari, respondents argued the same: the "specific information" petitioners failed to disclose was the "number of Zicam users" who reported experiencing anosmia after using the product. Opp. to Pet. for Cert. 16; *see id.* at 12, 17, 19; PB44 n.22.

The district court correctly rejected that theory. Simply alleging that a drug manufacturer received a small number of AERs tells one nothing about

whether random chance rather than causation is at work. *See Oran v. Stafford*, 226 F.3d 275, 284 (3d Cir. 2000) (Alito, J.). For this reason, four circuit decisions—including one issued just recently—have held that drug companies have no duty to disclose raw numbers of AERs absent factual allegations establishing that the raw numbers are scientifically meaningful. *See Detroit Gen. Ret. Sys. v. Medtronic, Inc.*, 621 F.3d 800, 807 (8th Cir. 2010); *N.J. Carpenters Pension & Annuity Funds v. Biogen IDEC Inc.*, 537 F.3d 35, 48-50 (1st Cir. 2008); *Oran*, 226 F.3d at 284; *In re Carter-Wallace, Inc. Sec. Litig.*, 150 F.3d 153, 157 (2d Cir. 1998).

As these courts recognize, no reasonable investor would find 12-23 AERs out of millions of products sold to be significant to an investment decision. Other than product-liability plaintiffs' lawyers, nobody—including the FDA—believes that AERs by themselves reliably indicate whether there is a causal link between a drug and an adverse event. PB17-25.

The AERs in this case are an especially implausible basis for establishing a material omission given not only the minuscule number of reports compared to the number of products sold, but also because of the common problem of confounding by indication. Because anosmia is mainly caused by the very condition for which consumers use Zicam (PB47 & n.24), "determining the direction of causation is difficult at best." *Robinson v. McNeil Consumer Healthcare*, 615 F.3d 861, 868 (7th Cir. 2010); *see* FDA, Center for Drug Evaluation and Research, Guidance for Industry: Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment § IV(E) (Mar. 2005),

2005 WL 3628217. Respondents say the background incidence rate and confounding by indication are matters for discovery and trial (RB33-34), but their own complaint expressly raises the problem of confounding by indication (J.A. 78a (¶ 38)), without alleging any basis on which Matrixx knew or could have known that it was Zicam—not the colds for which Zicam was being used—that caused the few reported anosmia incidents. PB47-48. Respondents are obliged to plead facts that would entitle them to recovery if true, *see Iqbal*, 129 S. Ct. at 1949, and because they do not plead facts distinguishing the incidence rate of anosmia among Zicam users from the rate among cold-sufferers, they have no legal basis for recovery.

The Solicitor General contends that raw AERs are material because the FDA sometimes acts on them before statistical significance is demonstrated, and thus a reasonable investor would want to know about the raw AERs. U.S. Br. 19. But the FDA has broad, subjective discretion in determining when to investigate further or to initiate regulatory activity. The agency is not limited to acting on information accurate and reliable enough to matter to a reasonable investor (or reliable enough for federal courts, *see* PB7 n.2). While the known, concrete fact of imminent FDA action may be material, companies cannot know in the abstract whether particular information creates a sufficient "signal" on which the agency may choose to act. The purely speculative possibility that the FDA might act cannot be the basis for reasonable investment decisions. *See Epstein v. Wash. Energy Co.*, 83 F.3d 1136, 1141 (9th Cir. 1996). This case vividly illustrates the point: the

FDA did not do anything until *more than five years* after the end of the class period, and it acted then only on the basis of accumulated information beyond the facts alleged in the complaint. And even now, the FDA says that the data remain "inconclusive." U.S. Br. 8. The few raw AERs Matrixx had received by February 6, 2004, plainly were nowhere close to triggering an agency response, and thus could not have triggered a disclosure obligation on the basis of imminent agency action.[3]

2. Respondents now offer a new theory of securities fraud, *viz.*, that even if AERs are insufficient as a class, the complaint here nevertheless alleged facts establishing materiality because it asserted additional "detailed and corroborated information" about a causal link between Zicam and anosmia. RB49 n.35. But the supposed additional information respondents cite is nothing more than "the user's loss of sense of smell following Zicam's application into the nose"—information received from "otolaryngology researchers, consumer complaints, and personal-injury lawsuits." RB49 n.35. Virtually everything else respondents now emphasize comes from sources outside the complaint. "It is axiomatic," however, "that the complaint may not be amended by the briefs in opposition to a motion to dismiss," *Pennsylvania ex rel. Zimmerman v. PepsiCo, Inc.*, 836 F.2d

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[3] The absence of prior FDA analysis of Zicam (U.S. Br. 30-31) does not make a handful of raw AERs a reliable basis for inferring causation. And even AERs concerning an FDA-reviewed drug likely would be material under the Solicitor General's "anything could matter to skittish consumers" view of materiality.

172 181 (3d Cir. 1988) (quotation omitted), and "[i]t is not ... proper to assume that [a plaintiff] can prove facts that it has not alleged." *Assoc. Gen. Contractors, Inc. v. Cal. State Council of Carpenters*, 459 U.S. 519, 526 (1983). Accordingly, "in reviewing [a] Rule 12(b)(6) dismissal of [a plaintiff's] claims, [an appellate court] may only look to the factual allegations asserted in the complaint." *Gordon v. Wawa, Inc.*, 388 F.3d 78, 84 (3d Cir. 2004). The district court here invited respondents to amend their complaint and plead more facts establishing materiality, but they refused, electing instead to pursue an appeal based entirely on Matrixx's failure to disclose the "numbers" of AERs it had received by February 6, 2004. This Court in turn granted certiorari to review the question whether AERs alone can be material absent statistical significance, and respondents raised no quarrel with that question in their opposition. S. Ct. Rule 15.2. It is too late now to recharacterize either their complaint or the materiality question it presents. *See Travelers Cas. & Sur. Co. of Am. v. Pac. Gas & Elec. Co.*, 549 U.S. 443, 455 (2007).

3. In any event, respondents' new theory does not salvage their complaint. Respondents contend that the AERs at issue here were material because they (i) were "voluntary [and] unregulated communications from knowledgeable specialists"; (ii) include "corroborating details"; (iii) are consistent with "background medical literature"; and (iv) involve a "serious[]" adverse event.[4] RB33, 55; *see* U.S. Br. 30-

[4] In the absence of reliable evidence of a causal link, the asserted seriousness of anosmia is irrelevant. *See supra* at 7-8.

31. Those facts fall well short of establishing any reliable basis for inferring causation under the detailed, multi-factor tests specialists and courts apply when epidemiological studies are not available. PB44 n.22.

a. Doctors have no special expertise in deducing causation simply because they can diagnose conditions. "The ability to diagnose medical conditions is not remotely the same ... as the ability to deduce ... in a scientifically reliable manner, the causes of those medical conditions." *Tamraz v. Lincoln Elec. Co.*, 620 F.3d 665, 673 (6th Cir. 2010) (quotation omitted; alteration in original); *see* Mary Sue Henifin et al., Reference Guide on Medical Testimony, *in* FJC Manual 471-72 ("[A]n expert's opinion on diagnosis and his or her opinion on external causation should generally be assessed separately[.]"). Respondents confuse the differential *diagnosis* of a treating physician (which identifies the condition that causes symptoms) with differential *etiology* (which identifies the cause of a condition). *See Tamraz*, 620 F.3d at 673-74. A differential etiology is reliable when it *both* "rul[es] out" potential causes (RB49), *and* rules in the suspected cause based on scientifically reliable evidence, which does *not* include doctors' case studies or mere temporal association. *See, e.g., Turner v. Iowa Fire Equip. Co.*, 229 F.3d 1202, 1208-09 (8th Cir. 2000); PB25.[5]

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[5] Notably, the "specialist" opinions of Jafek and others now cited by respondents have been consistently *rejected* by courts as unreliable. PB7 n.2.

Indeed, doctor-generated AERs do not by themselves reliably indicate causation even when they meet the FDA's criteria for a complete report—which the telephone calls alleged in respondents' complaint plainly do not. *See* FDA, The Clinical Impact of Adverse Event Reporting 5 (Oct. 1996) ("careful, thoughtful review" of clinical AERs is necessary before reliable determination of causation can be made).[6] "Case studies and clinical experience, used alone and not merely to bolster other evidence, are ... insufficient to show general causation." *Hendrix v. Evenflo Co.*, 609 F.3d 1183, 1197 (11th Cir. 2010).

b. Respondents argue the AERs discussed in Jafek's poster presentation were supported by "clinical evidence" in the form of a burning sensation following use of Zicam. RB28, 34. But the poster presentation was not attached to the complaint. And respondents alleged nothing drawing a clinical connection between the asserted burning sensation and anosmia, which involves olfactory tissues that lack pain nerves. *See, e.g.*, Michael Tal & Marshall Devor, Anatomy and Neurophysiology of Orofacial Pain, *in* Orofacial Pain & Headache § 2.4.2.1, at 24 (Yair Sharav & Rafael Benoliel, eds. 2008) ("The intense burning sensation that follows sniffing of irritating substances such as ammonia or spicy horse-

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[6] *Available at* http://www.fda.gov/downloads/Safety/MedWatch/UCM168505.pdf. The FDA's criteria for a complete AER include a "succinct clinical description of [the] adverse event, [with] confirmatory/relevant test/laboratory results" and a description of "confounding factors (such as concomitant medical products and medical history)." *Id.* at 5-6.

radish is thought to be due to the activation of trigeminal C-fibre chemo-nociceptors, not olfactory receptors."). Anyone who has had a foreign substance—even water—injected into his or her nose knows that burning and watery eyes can follow. Respondents' assumption that a burning sensation is connected to a subsequent loss of smell is classic *post hoc ergo propter hoc* reasoning. *See, e.g., McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1243 (11th Cir. 2005). Respondents also claim that Jafek rejected upper respiratory infections ("URIs") as a cause, but the complaint says no such thing, and his poster cites nothing to support that conclusion. The omission is unsurprising: the scientific literature unambiguously establishes a causal link between anosmia and URIs associated with the common cold. PB47 & n.24.

c. Respondents also insist they alleged facts establishing a "biologically plausible" link between Zicam and anosmia. RB28. But the complaint alleges only a "link between zinc *sulfate* and loss of smell." J.A. 69a (¶ 27) (emphasis added). The active ingredient in Zicam is zinc *gluconate*. The common element of zinc does not establish a common harm: carbon dioxide does not have the same effect on humans as carbon monoxide just because both have a carbon element. Respondents nevertheless contend that the complaint's reference to zinc sulfate suffices to allege a biological link between zinc gluconate and anosmia because a 1982 study of the "olfactory mucosa of catfish" (RB7) supposedly identified a link between zinc ions in *other* zinc salts (not even zinc gluconate) and anosmia in catfish. RB29 n.24. But respondents do not (and could not) explain how stud-

ies of a compound's effect on the olfactory mucosa of a nonmammalian species that lives and breathes only underwater could have any bearing on the effect of a different compound on human beings. *See* Bernard D. Goldstein & Mary Sue Henifin, Reference Guide on Toxicology, *in* FJC Manual 410-11.

4. Respondents offer two additional theories of materiality not tied to AERs as such.

First, they argue that the stock price movement following the *Good Morning America* story indicates the AERs themselves were material. RB30-31; U.S. Br. 31. But the *Good Morning America* broadcast reported that Jafek had reliably concluded that Zicam actually causes anosmia. Investors responded to *that* claim, not to the very different information Matrixx possessed. The fact that the stock price moved in response to a direct public declaration of causation on a major network news broadcast, as opposed to a handful of uncorroborated and unreliable AERs, does nothing to establish materiality. *See ECA*, 553 F.3d at 205 (allegation of actual stock drop is insufficient allegation of materiality); *Koncelik v. Savient Pharms., Inc.*, 2010 WL 3910307, at *10 (S.D.N.Y. Sept. 29, 2010).

Second, respondents argue that a lawsuit filed in October 2003 was material because it was an "early indication that Matrixx's flagship drug was now exposed to litigation." RB29-30 n.25. But a reasonable investor obviously would be aware that pharmaceutical companies are routinely exposed to product-liability litigation. Indeed, the impacts of such litigation are addressed in a distinct disclosure duty not implicated here. *See* Regulation S-K, 17 C.F.R.

§ 229.103. Nor is the October 2003 lawsuit rendered uniquely material by Matrixx's Form 10-Q statement that even frivolous lawsuits "could materially adversely affect" the company. J.A. 178a. A reasonable investor would be interested in a particular lawsuit only if there were an objective basis for believing that *that lawsuit* could affect the company. Respondents allege no such facts concerning the October 2003 lawsuit.

II. RESPONDENTS' ALLEGATIONS DO NOT CREATE A STRONG INFERENCE OF SCIENTER

Respondents' complaint also fails to plead facts sufficient to create a strong inference of scienter, i.e., an inference as "cogent and at least as compelling as any opposing inference of nonfraudulent intent." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 314 (2007).

The most compelling inference that can be drawn from the facts alleged is that Matrixx did not disclose the handful of AERs because they did not provide a reliable basis for inferring that Zicam causes anosmia. PB49-50. Respondents contend that an inference of fraudulent intent is equally compelling, but many of the facts they cite (RB34-38) appear nowhere in the complaint. Respondents cannot now rely on unalleged facts to challenge the dismissal of their complaint. *Supra* at 17.

For instance, respondents assert that "Matrixx attempted to stop Dr. Jafek from publishing" his findings in a poster presentation (RB35), but the complaint alleges no such thing. Instead the complaint alleges only that Matrixx informed Jafek that

he did not have Matrixx's permission to reference "Zicam" or "Matrixx" in the poster presentation. J.A. 61a (¶ 4). Nothing Matrixx said challenged Jafek's right to publish his "findings" concerning anosmia and "intranasal zinc gluconate," which he published without repercussion. Matrixx's statement related solely to the use of the Zicam brand, and there is nothing nefarious about protecting a brand's reputation from unverified public attack. Indeed, the shareholder class suing Matrixx would expect no less.

Respondents also now assert that Matrixx's attempts to obtain more information from Jafek and Linschoten were not made in good faith, claiming that "[t]he record will not bear that interpretation." RB36; *see* RB37 & n.33. But the relevant inquiry is what the *complaint* alleges, and it alleges nothing to suggest that Matrixx was doing anything other than what the complaint itself says—i.e., seeking more information from Jafek and Linschoten about the user complaints they had received, as respondents themselves concede. RB37 (acknowledging that "Matrixx's Vice President and Director of Research and Development personally followed up on communications with Drs. Linschoten and Jafek"). Contrary to respondents' submission, Matrixx could hardly have concluded that their "findings" were a "real concern for its business" (RB37), inasmuch as they were unwilling to provide information supporting those "findings."

Turning to facts actually alleged in the complaint, there is no merit to respondents' reliance on the findings of the scientific panel Matrixx convened after the close of the class period. RB37-38; *see* U.S.

Br. 32-33. The panel's conclusion—*viz.*, that there was "insufficient scientific evidence ... to determine if zinc gluconate, when used as recommended, affects a person's ability to smell," J.A. 82a (¶¶ 45-46), 206a—actually *confirmed* Matrixx's previously stated "belie[f]" that Jafek's affirmative declarations that Zicam causes anosmia were completely unfounded and misleading, J.A. 77a (¶ 38). Contrariwise, the panel's conclusion did *not* show that Matrixx knowingly made false statements about Zicam's safety during the class period. Those statements were based on the solid scientific foundation of two double-blind, placebo-controlled, randomized clinical trials of zinc gluconate, in which there were no reports of anosmia, and "the overall incidence of adverse events associated with zinc gluconate treatment was extremely low, with no statistically significant difference between the adverse event rates for the treated and placebo subsets." J.A. 117a; *see also* J.A. 62a, 77a-78a, 80a-82a, 86a, 193a-94a, 201a-02a, 261a. The subsequent panel did not reject those studies or condemn Matrixx's prior statements. It concluded only that the existing scientific evidence provided an insufficient basis for drawing affirmative conclusions one way or the other about Zicam and anosmia.

Matrixx's decision to convene a scientific panel to further examine the issue of anosmia after the *Good Morning America* segment is responsible corporate behavior the law should encourage. Allegations that a company took subsequent measures of this nature cannot support an inference of scienter in securities-fraud cases. *See Higginbotham v. Baxter Int'l, Inc.*, 495 F.3d 753, 760 (7th Cir. 2007) (rejecting, in secu-

rities-fraud case, allegation that defendant hired company to "beef up [its] financial controls" as supporting an inference of scienter because "[d]rawing any inference from this would be incompatible with Fed. R. Evid. 407, which provides that subsequent remedial measures may not be used as evidence of liability"); *accord Pugh v. Tribune Co.*, 521 F.3d 686, 695 (7th Cir. 2008).

CONCLUSION

For the foregoing reasons, the judgment of the court of appeals should be reversed.

Respectfully submitted,

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AMICUS CURIAE BRIEF

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In the Supreme Court of the United States

MATRIXX INITIATIVES, INC., ET AL., PETITIONERS

v.

JAMES SIRACUSANO, ET AL.

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
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BRIEF FOR THE UNITED STATES AS AMICUS CURIAE SUPPORTING RESPONDENTS

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QUESTION PRESENTED

Petitioner Matrixx Initiatives Inc. (Matrixx) sold an intranasally applied cold remedy (Zicam) that accounted for 70% of Matrixx's sales. Matrixx shareholders (respondents in this Court) allege that Matrixx violated Section 10(b) of the Securities Exchange Act of 1934, 15 U.S.C. 78j(b), and Rule 10b-5, 17 C.F.R. 240.10b-5, by touting Zicam's expected success and safety without disclosing, among other pertinent information, reports from physicians and researchers that some users had suffered a loss of their sense of smell (anosmia) after using Zicam. On the day that such reports became public, Matrixx's stock price dropped 23.8%. The question presented is as follows:

Whether, in order to state a Section 10(b) claim based on Matrixx's failure to disclose information regarding the possible association between use of Zicam and anosmia, respondents were required to allege evidence of a "statistically significant" association.

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In the Supreme Court of the United States

No. 09-1156

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ON WRIT OF CERTIORARI
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BRIEF FOR THE UNITED STATES AS AMICUS CURIAE SUPPORTING RESPONDENTS

INTEREST OF THE UNITED STATES

The United States, through the Department of Justice and the Securities and Exchange Commission (SEC), administers and enforces the federal securities laws, including the laws at issue in this case, Section 10(b) of the Securities Exchange Act of 1934 (Exchange Act), 15 U.S.C. 78j(b), and Rule 10b-5, 17 C.F.R. 240.10b-5. The question presented in this case may arise in both private and government actions.

STATEMENT

1. Section 10(b) of the Exchange Act makes it unlawful "[t]o use or employ, in connection with the purchase or sale of any security * * * , any manipulative or deceptive device or contrivance in contravention of"

rules promulgated by the SEC. 15 U.S.C. 78j(b). Under SEC Rule 10b-5, it is unlawful "[t]o make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading." 17 C.F.R. 240.10b-5(b). To state a claim under Section 10(b) and Rule 10b-5, the government or a private plaintiff must allege, as relevant here, that the false statement or misleading omission was "material" and that the defendant acted with scienter. See *Stoneridge Inv. Partners, LLC* v. *Scientific-Atlanta, Inc.*, 552 U.S. 148, 157 (2008).

A "fundamental purpose" of the Exchange Act "was to substitute a philosophy of full disclosure for the philosophy of *caveat emptor*." *Basic Inc.* v. *Levinson*, 485 U.S. 224, 234 (1988) (quoting *SEC* v. *Capital Gains Research Bureau, Inc.*, 375 U.S. 180, 186 (1963)). Balancing "the need to insure adequate disclosure" and "the need to avoid the adverse consequences of setting too low a threshold," the Court has construed the securities laws to incorporate the "conventional tort test of materiality." *TSC Indus., Inc.* v. *Northway, Inc.*, 426 U.S. 438, 445, 449 n.10 (1976). For purposes of Section 10(b) and Rule 10b-5, an omitted fact is "material" if there is "a substantial likelihood that a reasonable shareholder would consider it important." *Basic*, 485 U.S. at 231-232 (quoting *TSC Indus.*, 426 U.S. at 449).

Liability under Section 10(b) requires proof that the defendant acted with scienter, "a mental state embracing intent to deceive, manipulate, or defraud." *Ernst & Ernst* v. *Hochfelder*, 425 U.S. 185, 193 & n.12 (1976). Under the Private Securities Litigation Reform Act of 1995 (PSLRA), 15 U.S.C. 78u-4(b)(2), the plaintiff in a private Section 10(b) suit must plead with particularity,

inter alia, facts giving rise to a strong inference that the defendant acted with scienter. See *Tellabs, Inc.* v. *Makor Issues & Rights Ltd.*, 551 U.S. 308, 319 (2007).

2. a. Matrixx Initiatives, Inc. (Matrixx), a pharmaceutical company, sold over-the-counter cold remedies. One of its main products, Zicam Cold Remedy (Zicam), which contained zinc gluconate, was available in several forms including an intranasal gel and spray. During the period relevant to this case (October 22, 2003, to February 6, 2004), Zicam accounted for 70% of Matrixx's sales. J.A. 60a (¶ 2). Zicam, which was marketed as a homeopathic remedy, did not (and does not) have a new drug application approved by the Food and Drug Administration (FDA). J.A. 269a.[1]

b. By September 2003, three medical researchers and physicians had informed Matrixx that at least a dozen users of Zicam—including ten patients in a case study—had experienced a loss of their sense of smell, a condition known as anosmia.

In December 1999, Dr. Alan Hirsch, Neurological Director of the Smell & Taste Treatment and Research

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[1] FDA ordinarily exercises enforcement discretion to permit the marketing of homeopathic drugs without an approved new drug application under certain conditions consistent with FDA guidance. See FDA Compliance Policy Guide § 400.400, *Conditions Under Which Homeopathic Drugs May Be Marketed* (rev. Mar. 1995). That exercise of discretion, however, is not unlimited. In 2009, FDA issued a warning letter to Matrixx for marketing certain intranasal forms of Zicam without an approved new drug application in violation of 21 U.S.C. 331(d) and 355(a), stating that Zicam "may pose a serious risk to consumers" and specifically identifying reports of Zicam-associated anosmia. J.A. 268a-271a. In response, Matrixx withdrew the products at issue from the market. *Matrixx Initiatives Voluntarily Withdraws Zicam Cold Remedy Swabs, Zicam Cold Remedy Nasal Gel*, June 16, 2009, http://www.zicam.com/messagetoconsumers.

Foundation, contacted Matrixx about a possible link between Zicam and anosmia. Dr. Hirsch told Matrixx that at least one patient had developed anosmia after using Zicam in the absence of a cold, and that previous studies had demonstrated that intranasal application of zinc could be problematic. J.A. 67a-68a (¶ 25).

In September 2002, Dr. Miriam R. Linschoten of the University of Colorado spoke to Matrixx about one of her patients who had been treated for anosmia after using Zicam. Matrixx informed Dr. Linschoten that it had received complaints from others. Dr. Linschoten sent Matrixx abstracts from published studies on the link between another zinc compound (zinc sulfate) and anosmia. J.A. 68a-69a (¶¶ 26-27).

In September 2003, Matrixx learned that a third researcher, Dr. Bruce Jafek of the University of Colorado (in conjunction with Dr. Linschoten and another colleague), planned to make a poster presentation entitled "Zicam® Induced Anosmia" to the American Rhinologic Society later that month. The poster, reporting on their study involving ten patients who had developed anosmia after using Zicam, described in detail how one patient had experienced a severe burning sensation and loss of smell immediately after using Zicam. Matrixx demanded that Dr. Jafek remove the references identifying Zicam by name, and he presented the poster without such references. J.A. 69a-70a (¶¶ 28-29).

c. In an October 2003 press release and conference call, Matrixx stated that Zicam was "poised for growth in the upcoming cough and cold season"; that Zicam was the engine behind the company's "very strong momentum going into the upcoming cough and cold season"; that Matrixx was "extremely well positioned for a successful 2003/2004 cough/cold season"; and that the com-

pany expected revenues to increase by 50%. J.A. 71a-75a (¶¶ 32-34).

On November 12, 2003, Matrixx filed a Form 10-Q with the SEC. Matrixx stated that even a single unmeritorious product liability claim "could materially adversely affect our results of operations and financial condition." J.A. 75a-76a (¶ 35). Matrixx did not disclose that it had already been sued by two plaintiffs who claimed to have suffered anosmia due to Zicam use. *Ibid.*

On February 2, 2004, in response to a January 30 news report linking Zicam and anosmia (J.A. 188a-192a), Matrixx issued a press release in which it asserted that "statements alleging that intranasal Zicam products cause anosmia (loss of smell) are completely unfounded and misleading" because "the safety and efficacy of zinc gluconate" were "well established" by two clinical trials. J.A. 77a-78a (¶ 38) (quoting J.A. 193a-195a).

On February 6, 2004, the television program *Good Morning America* reported on the possible link between Zicam use and anosmia. That day, the price per share of Matrixx stock fell from $13.05 to $9.94—a single-day drop of 23.8%. J.A. 81a (¶ 43).

Also on February 6, Matrixx issued another press release reiterating that Zicam's safety had been "well established." J.A. 81a-82a (¶ 44). Later that month, however, Matrixx acknowledged (in a Form 8-K filing with the SEC) that a panel of scientists convened "to review current information on smell disorders" had concluded that "there is insufficient scientific evidence at this time to determine if zinc gluconate, when used as recommended, affects a person's ability to smell." J.A. 82a (¶¶ 45-46), 206a.

By October 2004, Matrixx had been sued by approximately 284 individuals in 19 different lawsuits alleging that Zicam had caused damage to their sense of smell. Four such lawsuits (involving nine individuals) were filed before February 6, the date of the *Good Morning America* report. J.A. 87a-88a.

3. a. Respondents filed this class action under Section 10(b) and Rule 10(b)-5 on behalf of investors who had purchased Matrixx stock between October 22, 2003, and February 6, 2004. The named defendants (petitioners in this Court) were Matrixx and three of its officers. Respondents alleged, *inter alia*, that Matrixx's predictions of Zicam's commercial success were materially misleading because Matrixx had concealed a risk of anosmia that could (and did) affect Matrixx's stock price; that Matrixx's Form 10-Q filing was materially misleading because it failed to disclose a pending lawsuit claiming that Zicam caused anosmia; and that Matrixx's statements about scientific evidence establishing Zicam's safety were materially misleading because, as Matrixx later acknowledged, there was insufficient evidence to make that determination. J.A. 58a-111a.

b. The district court dismissed respondents' complaint. Pet. App. 35a-54a. Citing *In re Carter-Wallace, Inc.*, 220 F.3d 36 (2d Cir. 1998), the district court stated that "adverse information related to the safety of a product is not material unless such reports provide reliable statistically significant information that a drug is unsafe." Pet. App. 45a. The court found that "12 user complaints is not statistically significant" and that respondents had therefore "failed to present evidence of a statistically significant correlation between the use of Zicam and anosmia." *Id.* at 50a. The district court further ruled that respondents' allegations of scienter

failed to satisfy the PSLRA's heightened pleading standard. *Id.* at 50a-54a.

4. The court of appeals reversed and remanded. Pet. App. 1a-34a.

a. The court of appeals held "that the district court erred in relying on the statistical significance standard to conclude that [respondents] failed adequately to allege materiality." Pet. App. 23a. The court explained that "[a]n omitted fact is material if there is a substantial likelihood that a reasonable shareholder would consider it important," *id.* at 21a-22a (quoting *TSC Indus.*, 426 U.S. at 449), and it noted this Court's rejection of bright-line materiality rules in *Basic*, *id.* at 23a. The court of appeals reasoned that by using the "statistical significance" standard, the district court had "made a decision that should have been left to the trier of fact." *Id.* at 24a. After "engag[ing] in the fact-specific inquiry required by *Basic*," and in light of all the allegations in the complaint, the court of appeals concluded that the respondents had "sufficiently alleged materiality." *Id.* at 24a-26a.

b. The court of appeals also rejected the district court's determination that respondents had failed adequately to allege scienter. Pet. App. 26a-34a. The court explained that at the time Matrixx had "touted the potential for growth and profitability of Zicam" and alerted investors generally to the risks of litigation, Matrixx (1) knew that at least a dozen Zicam users had developed anosmia, (2) was aware that past studies linked another zinc compound to anosmia, (3) had prevented Dr. Jafek from using Zicam's name in a research presentation, and (4) was defending itself in an anosmia-related lawsuit. *Id.* at 32a. Moreover, the court noted, Matrixx had represented that clinical trials had estab-

lished the safety of Zicam even "though it was subsequently reported that Matrixx had not conducted such studies." *Id.* at 32a-33a. Based on those allegations, the court concluded that "the inference of scienter is 'cogent and at least as compelling' as any 'plausible non-culpable explanation' for [petitioners'] conduct," and that respondents therefore satisfied the PSLRA's standard for pleading scienter. *Id.* at 33a-34a (quoting *Tellabs*, 551 U.S. at 324).

SUMMARY OF ARGUMENT

A. Materiality is a touchstone of liability under Section 10(b) and Rule 10b-5, and this Court has held that an omitted fact is "material" when there is a substantial likelihood that a reasonable investor would have considered it important. *Basic Inc.* v. *Levinson*, 485 U.S. 224, 231-232 (1988). Petitioners propose to depart from that settled understanding in favor of a categorical rule that deems information about an adverse effect associated with use of a drug immaterial unless the association is statistically significant.

1. That rule conflicts with *Basic*'s standard for two important reasons. First, evidence other than data showing a statistically significant association can suggest a causal link between use of a drug and an adverse effect. Medical researchers, courts, and FDA regularly consider multiple factors in assessing causation, especially where (as here) the available epidemiological data are inconclusive. Second, a reasonable investor may consider information suggesting an adverse drug effect important even if it does not prove that the drug causes the effect. Even reports that simply suggest causation may affect the behavior of consumers, potential litigants, and FDA. Because such reactions can affect a

product's commercial viability, and thus the company's financial condition, a reasonable investor often will want to know about such information.

2. Petitioners' proposed rule also conflicts with this Court's precedents because it establishes a rigid restriction, particularly at the pleading stage. This Court previously rejected a "bright-line" rule both because it was too underinclusive and because the materiality inquiry requires "delicate assessments" better suited to the trier of fact. *Basic*, 485 U.S. at 236; *TSC Indus., Inc.* v. *Northway, Inc.*, 426 U.S. 438, 450 (1976). Even in product-liability cases, where causation is an element, courts look beyond statistical significance, and petitioners cite no case that was dismissed for lack of statistical significance at the pleading stage.

3. The inquiry described in *Basic* provides adequate guidance to courts and companies. In *Basic*, this Court rejected the same policy argument that petitioners advance here, *i.e.*, that their bright-line rule is necessary to avoid inundating the market with irrelevant disclosures. 485 U.S. at 234. That argument is particularly unpersuasive here in light of FDA-reporting requirements for drug companies and FDA's policy of making adverse event data publicly available. As this Court explained, courts can look to several illustrative factors to determine whether allegations of materiality are sufficient to survive a motion to dismiss in this context. Doing so will screen out unmeritorious claims.

4. Respondents' complaint adequately alleges materiality. First, the source of most of the adverse information was not random users but experts in the field, based on their clinical observation of at least a dozen cases of anosmia in Zicam users and published studies establishing a link between anosmia and another zinc compound.

Second, drug-induced anosmia is a serious side effect, especially relative to any benefit provided by Zicam. Third, Zicam did not undergo pre-market evaluation by FDA and was marketed without FDA approval. Fourth, the temporal relationship between Zicam use and anosmia, its intranasal application, and the prior zinc studies suggest a plausible link. Fifth, Zicam, which accounted for 70% of Matrixx's sales at the time, was crucial to Matrixx's success, as confirmed by the 23.8% drop in stock price on the day the information was disclosed.

B. For similar reasons, a plaintiff need not allege statistical significance in order to plead scienter. The PSLRA requires a private Section 10(b) plaintiff to plead with particularity facts showing a "strong inference" of scienter, 15 U.S.C. 78u-4(b)(2), *i.e.*, an inference "cogent and at least as compelling as any opposing inference of nonfraudulent intent." *Tellabs, Inc.* v. *Makor Issues & Rights, Ltd.*, 551 U.S. 308, 314 (2007). The facts alleged in respondents' complaint, including Matrixx's intervention to stop Dr. Jafek from using Zicam's name in an academic presentation and its misrepresentations and omissions regarding a pending product-liability lawsuit and Zicam's "well established" safety, satisfy that standard.

ARGUMENT

RESPONDENTS HAVE ADEQUATELY PLEADED THAT PETITIONERS' PUBLIC STATEMENTS CONTAINED MATERIAL OMISSIONS AND THAT PETITIONERS ACTED WITH SCIENTER

A. Information Suggesting That A Drug Causes An Adverse Effect May Be "Material" To Investors Even Absent Statistical Significance

Under this Court's precedents, an omitted fact is "material" for securities-fraud purposes if there is "a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information available." *Basic Inc.* v. *Levinson*, 485 U.S. 224, 231-232 (1988) (quoting *TSC Indus., Inc.* v. *Northway, Inc.*, 426 U.S. 438, 449 (1976)). That inquiry generally requires "delicate assessments of the inferences a 'reasonable shareholder' would draw from a given set of facts and the significance of those inferences to him," and those assessments are "peculiarly ones for the trier of fact." *TSC Indus., Inc.*, 426 U.S. at 450.

Petitioners urge this Court to bypass that contextual inquiry altogether in cases where a Section 10(b) claim is premised on a company's failure to disclose information about adverse effects associated with use of its drug. Petitioners would replace the nuanced approach described above with a categorical rule that such information is immaterial unless a "statistically significant" association is alleged. As this case indicates, however, information suggesting a causal link between use of a drug and a serious adverse effect may significantly alter the behavior of consumers, regulators, and product-liability plaintiffs, even when there is no allegation of a

statistically significant association. Because those reactions can affect a company's financial well-being, and its share price, reasonable investors would consider such information to be highly relevant to their investment decisions. Under the approach described in *Basic*, respondents adequately alleged that petitioners' public statements contained material omissions.

1. Reasonable investors or potential investors in a drug company may be concerned about information that raises concerns about the safety of the company's products, even when that information does not establish a "statistically significant" association

Petitioners contend (1) that proof of a statistically significant association is the only "scientifically reliable basis for inferring a causal link between the product use and the [adverse] event," and (2) that a reasonable investor would consider information suggesting a potential link between a drug and an adverse event to be important only if such proof existed. Pet. Br. 13-14, 15-16. Both of those contentions are incorrect.

First, data showing a statistically significant association are not essential to establish a link between use of a drug and an adverse effect. As petitioners ultimately acknowledge (Br. 44 n.22), medical researchers, regulators, and courts consider multiple factors in assessing causation. Second, information suggesting an adverse drug effect may be important to a reasonable investor even if it does not prove that a causal link exists. Such information may affect the behavior of consumers and potential litigants, and FDA can and does take regulatory action without evidence establishing statistical significance. Because those responses affect a product's commercial viability, and thus the company's financial

condition, a reasonable investor often will want to know about such information.

a. Statistical significance is a limited and non-exclusive tool for inferring causation

Statistical significance is not synonymous with practical significance. Statistical significance is a measure of whether data indicate that two variables "occur together more frequently than one would expect by chance." Michael D. Green, Michael Freedman & Leon Gordis, *Reference Guide on Epidemiology*, in *Reference Manual on Scientific Evidence* 333, 348, 354 (2d ed. 2000) (*Reference Guide on Epidemiology*). For any association between a drug and a harm observed in a sample, there are many possible explanations for why the subjects that used the drug had a higher incidence of harm than those that did not. One explanation is that the drug causes the harm, but other potential explanations, including chance, exist. Statistical significance speaks solely to the probability that chance explains an observed association. Richard Lempert, *The Significance of Statistical Significance*, 34 Law & Soc. Inquiry 225, 232 (2009) (Lempert).

To assess statistical significance in the medical context, a researcher begins with the "null hypothesis," *i.e.*, that there is no relationship between the drug and the adverse effect. The researcher calculates a "p-value," which is the probability that the association observed in the study would have occurred even if there were in fact no link between the drug and the adverse effect. If that p-value is lower than the "significance level" selected for the study, then the results can be deemed statistically significant.

The significance level most commonly used in medical studies is 0.05. If the p-value is less than 0.05, there is less than a 5% chance that the observed association between the drug and the effect would have occurred randomly, and the results from such a study are deemed statistically significant. Conversely, if the p-value is greater than 0.05, there is greater than a 5% chance that the observed association would have occurred randomly, and the results are deemed not statistically significant. See *Reference Guide on Epidemiology* 357-358; David Kaye & David A. Freedman, *Reference Guide on Statistics*, in *Reference Manual on Scientific Evidence* 123, 123-125 (2d ed. 2000) (*Reference Guide on Statistics*).

While statistical significance provides some indication about the validity of a correlation between a product and a harm, a determination that certain data are not statistically significant—let alone, as here, the absence of any determination one way or the other—does not refute an inference of causation. See Michael D. Green, *Expert Witnesses and Sufficiency of Evidence in Toxic Substances Litigation: The Legacy of Agent Orange and Bendectin Litigation*, 86 Nw. U. L. Rev. 643, 682-683 (1992). Take, for example, results from a study, with a p-value of 0.06, showing that those who take a drug develop a rare but serious adverse effect (*e.g.*, permanent paralysis) three times as often as those who do not. Because the p-value exceeds 5%, the study's results would not be considered statistically significant at the 0.05 level. But since the results indicate a 94% likelihood that the observed association between the drug and the effect would *not* have occurred randomly, the data would clearly bear on the drug's safety. Upon release of such a study, "confidence in the safety of the drug in question should diminish, and if the drug were impor-

tant enough to [the issuer's] balance sheet, the price of its stock would be expected to decline." Lempert 239.[2]

The observed association may not be statistically significant for reasons other than the lack of a causal connection, including sample size and methodology. See *Reference Guide on Statistics* 122-126. In some circumstances—*e.g.*, where an adverse effect is subtle or has a low rate of incidence—an inability to obtain a data set of appropriate quality or quantity may preclude a finding of statistical significance. *Ibid.* That does not mean, however, that researchers have no basis on which to infer a plausible causal link between a drug and an adverse effect.

More broadly, causation can appropriately be inferred through consideration of multiple factors independent of statistical significance. In a footnote, petitioners acknowledge that critical fact:

> [C]ourts permit an inference of causation on the basis of scientifically reliable evidence other than statistically significant epidemiological data. In such cases experts rely on a lengthy list of factors to draw reliable inferences, including, for example, (1) the "strength" of the association, including "whether it is statistically significant"; (2) temporal relationship between exposure and the adverse event; (3) consis-

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[2] The same principle applies to studies suggesting that a particular drug is efficacious. A study in which the cure rate for cancer patients who took a drug was twice the cure rate for those who took a placebo could generate meaningful interest even if the results were not statistically significant. See Jonathan A.C. Sterne & George Davey Smith, *Sifting the evidence - what's wrong with significance tests?*, 322 British Med. J. 226, 227 (2001) (overemphasis on statistical significance may cause "clinically important differences" to be incorrectly "denoted as non-significant and ignored").

> tency across multiple studies; (4) "biological plausibility"; (5) "consideration of alternative explanations" (i.e., confounding); (6) "specificity" (i.e., whether the *specific* chemical is associated with the *specific* disease at issue); and (7) dose-response relationship (i.e., whether an increase in exposure yields an increase in risk).

Pet. Br. 44 n.22 (citations omitted). Those and other factors for inferring causation have been well recognized in the medical literature and by the courts of appeals. See, *e.g.*, *Reference Guide on Epidemiology* 345-347 (discussing relevance of toxicologic studies), 375-379 (citing, *e.g.*, Austin Bradford Hill, *The Environment and Disease: Association or Causation?*, 58 Proc. Royal Soc'y Med. 295 (1965)); *Best* v. *Lowe's Home Centers, Inc.*, 563 F.3d 171, 178 (6th Cir. 2009) ("an 'overwhelming majority of the courts of appeals' agree" that differential diagnosis, a process for medical diagnosis that does not entail statistical significance tests, informs causation) (quoting *Westberry* v. *Gislaved Gummi AB*, 178 F.3d 257, 263 (4th Cir. 1999)); *Ferebee* v. *Chevron Chem. Co.*, 736 F.2d 1529, 1536 (D.C. Cir.) ("[P]roducts liability law does not preclude recovery until a 'statistically significant' number of people have been injured."), cert. denied, 469 U.S. 1062 (1984). As discussed below (see pp. 19-20, *infra*), FDA relies on a number of those factors in deciding whether to take regulatory action based on reports of an adverse drug effect.

That criteria other than statistical significance are used to infer causation exposes the dramatic underinclusiveness of petitioners' proposed materiality standard. Petitioners contend (Br. 45 n.22) that "[t]his case does not present the question whether a securities fraud case can be premised on nondisclosure of information

establishing a causal inference on the basis of [the additional] criteria" described above. That is incorrect. As discussed below (see pp. 30-31, *infra*), respondents' complaint alleges facts that were known to Matrixx during the relevant time period and that suggest a potential causal link between Zicam use and anosmia.

b. Information suggesting a possible link between a drug and an adverse effect may alter the behavior of consumers, regulators, and potential product-liability plaintiffs, even absent statistically significant evidence of causation

"[T]he role of the materiality requirement" in a securities-fraud case is "to filter out essentially useless information that a reasonable investor would not consider significant." *Basic*, 485 U.S. at 234. As indicated by their reliance on product-liability cases (Br. 23-25, 37-39), petitioners conflate that materiality standard with the more demanding requirement applicable in a product-liability suit, *i.e.*, that the plaintiff prove that the allegedly defective product more likely than not caused the injury.[3]

Information suggesting that a company's product causes harm may be important to an investor even if the information does not establish that the causal link more likely than not exists. A reasonable investor cares about the impact undisclosed information will have on the company's finances and stock price. The extent of that impact depends on the conduct of consumers, regulators, and possible tort plaintiffs. Because those actors may respond in ways that hurt the company based on information that suggests but does not prove that the com-

[3] As noted above (pp. 15-16, *supra*), even causation in a product-liability claim may be proven without statistical significance.

pany's product causes a particular harm, there are many reasons why an investor would want to be alerted to the existence of such information.

First, reasonable consumers may decline to buy products that they perceive as risky, even though the available evidence does not suggest that it is "more likely than not" that the product causes harm. That is particularly true when the possible adverse effect is relatively serious and the benefit associated with the product is modest and/or available from a competing product. For example, publicity about children born with physical deformities after their mothers took an anti-nausea drug (Bendectin) sharply diminished the drug's sales despite FDA's contemporaneous finding that no causal link existed. The company, which at one point sold three million doses annually, eventually stopped making the drug. See *Company Stops Making Morning Sickness Drug*, N.Y. Times, June 10, 1983, at A16 (*Company Stops Making Drug*).[4] Under petitioners' proposed rule, however, a company that concealed information concerning such adverse events—or even a company that falsely stated that no such events had occurred (see pp. 24-25, *infra*)—would be immune from Section 10(b) liability.

Second, reports of serious adverse events often attract regulatory attention even absent statistically significant evidence of causation. Such regulatory attention can have a significant impact on a drug's commercial success and litigation risk. Petitioners understate

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[4] This phenomenon is not limited to the health product context. Audi's sales dropped more than 80% in the five-year period following a *60 Minutes* segment suggesting that Audi vehicles accelerated without warning, even though those claims were never proven true. Joseph P. White & Dionne Searcey, *Audi Case Set Template for Toyota's Troubles*, Wall. St. J., Mar. 12, 2010, at B1.

the importance of adverse event reports by emphasizing their limitations without explaining the manner in which FDA actually uses such reports.

Adverse event reporting is a critical element of FDA's post-market surveillance program. FDA receives these reports directly from health-care professionals, researchers, consumers, and others (*e.g.*, family members and lawyers), as well as from manufacturers (which generally must forward them to FDA subject to mandatory reporting rules, see p. 26, *infra*). FDA employs a multi-disciplinary staff of safety evaluators, epidemiologists, and other scientists to review adverse event data by a variety of methods, including the application of computer algorithms as well as scrutiny of individual reports. When the review identifies a "safety signal"—often in the form of a serious, rare, and/or unexpected adverse event—FDA further investigates the drug and its link to that event. See FDA, *The Clinical Impact of Adverse Event Reporting* 6-7 (1996), http://www.fda.gov/downloads/ Safety/MedWatch/UCM168505.pdf (*Adverse Event Reporting*).

As petitioners acknowledge (Br. 23), FDA does not apply any single metric for determining when additional inquiry or action is necessary, and it certainly does not insist upon "statistical significance." See *Adverse Event Reporting* 7. Indeed, statistical significance is not a scientifically appropriate or meaningful standard in evaluating adverse event data outside of carefully designed studies. *Id.* at 5; cf. Lempert 240 ("it is meaningless to talk about receiving a statistically significant number" of complaints). Rather, in exercising its scientific judgment based on the facts and circumstances of each case, FDA relies on a range of factors including: (1) strength of the association; (2) temporal relationship;

(3) consistency across data sources; (4) dose-response effect; (5) biologic plausibility; (6) seriousness of event relative to disease being treated; (7) potential to mitigate risk in the population; (8) feasibility of observational or clinical study designs; and (9) benefit the product provides, including availability of other therapies. FDA, *Guidance for Industry: Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment* 18 (2005), http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm071696.pdf (*Good Pharmacovigilance Practices*).

Based on its analysis, FDA may take an array of regulatory actions—*e.g.*, issuing a warning letter, revising product labeling, communicating new safety information to the public, and removing the product from the market. See FDA, *Adverse Event Reporting System (AERS)*, http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/adversedrugeffects/default.htm. By way of example, in June 2009, FDA issued a warning letter to Matrixx. J.A. 267a-274a. Among other violations, FDA stated that Zicam was misbranded because its labeling lacked "adequate warnings regarding the risk of anosmia." J.A. 271a (citing 21 U.S.C. 321(n) (taking into account whether the labeling omits "material" facts)). FDA did not cite statistically significant evidence of an association between Zicam and anosmia. Rather, FDA cited its receipt of more than 130 reports of anosmia associated with Zicam use; the relative paucity of such reports for other widely-used intranasal cold products; and the scientific literature analyzing the effect of zinc on olfactory function. J.A. 270a. Despite petitioners' characterization of adverse event reports as "inherently unreliable"

(Br. 20, 29), FDA thus takes a much more nuanced, context-specific approach.

FDA's reliance on adverse event reports as bases for regulatory action has significant practical consequences for marketing of the targeted product. In its November 2003 Form 10-Q filing, Matrixx identified as a risk factor that "FDA and other government regulation may restrict our ability to sell our products." J.A. 175a. And in response to the FDA warning letter issued in June 2009, Matrixx withdrew altogether the intranasal forms of Zicam from the market. See note 1, *supra*.

Third, when users of a drug experience an adverse event, a company may face product-liability litigation and incur related expenses, even if reliable proof of causation is lacking. These expenses include the direct costs of defending against claims (including experts, discovery, and attorney's fees) and paying settlements and judgments, as well as the indirect costs of harm to product reputation and higher insurance rates. See, *e.g.*, *Company Stops Making Drug*, *supra* (citing rising insurance premiums and cost of defending product-liability lawsuits); Gardiner Harris, *FDA Warns Against Use of Popular Cold Remedy*, N.Y. Times, at A14 (June 17, 2009) (noting that Matrixx settled some anosmia-based lawsuits for $12 million in 2006). Indeed, in its Form 10-Q filing, Matrixx acknowledged that even meritless product-liability suits could harm the company financially. J.A. 178a. A reasonable investor would therefore attach significance to information bearing on the likelihood that such suits might be filed.

2. A statistical significance test for materiality conflicts with this Court's decision in* Basic *and is particularly problematic at the pleading stage

Because petitioners' rigid "statistical significance" requirement does not capture information to which a reasonable investor would attach importance (Part A.1, *supra*), it contravenes this Court's analysis of materiality in securities-fraud cases. In *Basic*, the Court rejected a proposed standard under which the existence of preliminary merger discussions would be treated as material only when the merger partners had reached "agreement in principle" on a price and structure for the transaction. 485 U.S. at 232-236. The Court explained that, while such a "bright-line" rule is "easier to follow than a standard that requires the exercise of judgment in light of all the circumstances," "[a]ny approach that designates a single fact or occurrence as always determinative of an inherently fact-specific finding such as materiality, must necessarily be overinclusive or underinclusive." *Id.* at 236. This Court noted that courts "would do well to heed th[e] advice" of the Advisory Committee on Corporate Disclosure that materiality is "judgmental in nature and it is not possible to translate this into a numerical formula." *Ibid.* (quoting *Report of the Advisory Committee on Corporate Disclosure to the SEC*, 95th Cong., 1st Sess. 327 (1977)).[5]

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[5] In any event, petitioners are wrong in suggesting that a "statistical significance" standard would eliminate difficulties of administration. Statistical significance is a function of research design, which in turn is a function of various choices and assumptions about which qualified experts can and do frequently disagree. See *International Bhd. of Teamsters* v. *United States*, 431 U.S. 324, 340 (1977) (statistics "come in infinite variety," and "their usefulness depends on all of the surrounding facts and circumstances"). Statistical signficance does not resolve certain methodological concerns, such as "bias" in the selection of study subjects or "confounding variables." *Reference Guide on Epidemiology* 363-373. Petitioners do not commit to a specific significance level, and they suggest that drug companies should be permitted

Petitioners' proposed statistical significance rule would have the very same defects that this Court identified in *Basic*, and is even more problematic because it would mandate dismissal of suits *at the pleading stage*. A determination of materiality generally "requires delicate assessments of the inferences a 'reasonable shareholder' would draw from a given set of facts," and such "assessments are peculiarly ones for the trier of fact." *TSC Indus.*, 426 U.S. at 450. Dismissal of a Section 10(b) claim on materiality grounds is therefore appropriate only when the alleged omissions "are so obviously unimportant to a reasonable investor that reasonable minds could not differ on the question of their importance." *ECA* v. *J.P. Morgan Chase Co.*, 553 F.3d 187, 197 (2d Cir. 2009).

Under petitioners' proposed rule (Br. 48), a plaintiff must at least allege facts establishing that the rate of reported adverse events exceeds the background rate of incidence "by a statistically significant degree." As explained above (see p. 19, *supra*), however, adverse event reports do not lend themselves to a statistical-significance analysis. At a minimum, the standard petitioners advocate would require the design of a scientific study able to capture the relative rates of incidence (either through a clinical trial or observational study); enough participants and data to perform such a study and make it powerful enough to detect any increased incidence of the adverse effect; and a researcher equipped and interested enough to conduct it. Nothing in this Court's decisions suggests that respondents must undertake that

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to challenge the premises underlying an allegation of statistical significance. Pet. Br. 33 n.15 (arguing that statistically significant evidence is "not *necessarily* material" because "the underlying data may be flawed"), 35-36.

"difficult, time-consuming, and expensive" process, *Reference Guide on Epidemiology* 346, to demonstrate that reasonable investors would have attached significance to information casting doubt on Zicam's safety. And it would be particularly inappropriate to impose that burden at the pleading stage, especially where, as here, the drug company possesses pertinent information that plaintiffs and researchers might be unable to access without discovery. See J.A. 272a (noting Matrixx's possession of 800 reports apparently not disclosed to FDA); Pet. Br. 18-19 (asserting that company was not required during the class period to report adverse Zicam-related events to FDA).

Plaintiffs in other contexts are not subject to comparable pleading requirements. Petitioners cite dozens of cases from various areas of the law (Br. 38-42)—including products liability, employment discrimination, jury selection, and voting rights—but they identify not a single case that was dismissed at the pleading stage for failure to allege statistical significance. Indeed, as noted above (pp. 15-16, *supra*), courts do not view the lack of statistically significant evidence as dispositive even at later stages of litigation. Rather, statistical significance is simply one of many factors considered in deciding whether an expert's testimony is admissible or whether scientific evidence is sufficient to support a finding of causation.

Moreover, although this case involves principally the *nondisclosure* of information that was potentially relevant to respondents' investment decisions, petitioners' proposed materiality standard would apply equally to affirmative misrepresentations about facts bearing on the safety of drugs and other consumer products. For a securities-fraud claim, the false or misleading nature

of a statement (or omission) is not enough, without materiality, to trigger liability. See *Basic*, 485 U.S. at 238 ("[I]t is not enough that a statement is false or incomplete, if the misrepresented fact is otherwise insignificant."). Under petitioners' view, facts about adverse drug effects are *per se* immaterial absent statistically significant data. "[B]y definition, then, information concerning [such facts] could be withheld *or even misrepresented* without a violation of Rule 10b-5." *Id.* at 233 (emphasis added). Under that approach, a company that received credible reports of a rare but serious adverse effect associated with use of its drug could falsely represent that it was unaware of any such complaints, and nevertheless obtain dismissal of a Section 10(b) suit filed against it, unless the reports were substantiated by evidence of a statistically significant association.

3. ***Basic's materiality inquiry does not result in over-disclosure and appropriately filters out unmeritorious claims***

Petitioners' primary policy-based defense of their proposed statistical significance standard is that companies would otherwise be compelled to disclose all reports of adverse events, inundating the market with useless or suspect information and thereby undermining reasoned investment decisionmaking. Pet. Br. 26-32. This Court "soundly rejected" a comparable rationale for the "bright-line" rule proposed in *Basic*. 485 U.S. at 234. The Court explained that "[d]isclosure, and not paternalistic withholding of accurate information, is the policy chosen and expressed by Congress." *Ibid.* Rather than "assume[] that investors are nitwits, unable to appreciate—even when told—that" adverse event reports by themselves do not establish a conclusive causal link,

courts should trust investors to make informed decisions. *Ibid.* (citation omitted).

Petitioners' concern that indiscriminate release of adverse event reports will mislead investors is particularly unpersuasive in light of statutory and regulatory requirements that drug manufacturers report those events to FDA, and FDA's policy of making those reports publicly available. For all drugs with an approved new drug application as well as for prescription drugs without an approved new drug application, FDA has long required companies to report post-marketing "adverse drug experiences." 21 C.F.R. 314.80, 310.305. In 2006, Congress required manufacturers of non-prescription drugs without approved new drug applications to submit reports of "serious adverse events." 21 U.S.C. 379aa. And since 1998, FDA has made the raw adverse event data publicly available in electronic files (initially through the National Technical Information Service, a government clearinghouse, and, since 2004, through the FDA's own website). Petitioners' contention that such reports are more likely to mislead than to inform the public is thus directly contrary to FDA's considered judgment.[6]

In any event, affirmance of the court of appeals' judgment would not mean that drug companies must

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[6] Because Zicam was a non-prescription drug marketed without an approved new drug application, it was not subject to any of the aforementioned FDA-reporting requirements during the class period (which predated Section 379aa's enactment). See Pet. Br. 18-19. In circumstances where adverse event reports have been submitted to FDA and then made available to the public, however, the drug companies involved could be expected to defend against a fraud-by-omission claim by arguing that the adverse information has already been disseminated to the market via FDA. See, *e.g.*, Pharmaceutical Research & Manufacturers of Am. Amicus Br. 16-17 & n.5.

disclose to investors every isolated report of an adverse event. As an initial matter, the securities laws require disclosure only in limited situations. In particular, a drug company can choose simply to remain silent about the safety and prospects of its product and avoid any obligation to disclose potentially conflicting information. See *Basic*, 485 U.S. at 239 n.17 ("Silence, absent a duty to disclose, is not misleading under Rule 10b-5."). A duty to disclose arises only when a company chooses to make affirmative representations, including predictive statements about product success and safety, that are incomplete and misleading without omitted information. See 17 C.F.R. 240.10b-5(b) (making it unlawful "to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading"); see also, *e.g.*, *Helwig* v. *Vencor*, 251 F.3d 540, 561 (6th Cir. 2001) ("With regard to future events, uncertain figures, and other soft information, a company may choose silence or speech elaborated by the factual basis as then known—but it may not choose half-truths.").

Even when a company has spoken, it need not indiscriminately release all conceivably relevant information in order to avoid potential Section 10(b) liability. In *Basic*, after rejecting the proposed "bright-line" rule, this Court sought to guide courts' application of the "reasonable investor" materiality standard to speculative information or events. "Under such circumstances," the Court explained, "materiality 'will depend at any given time upon a balancing of both the indicated probability that the event will occur and the anticipated magnitude of the event in light of the totality of the company activity.'" *Basic*, 485 U.S. at 238 (quoting *SEC* v. *Texas Gulf Sulphur Co.*, 401 F.2d 833, 849 (2d Cir. 1968) (en banc),

cert. denied, 394 U.S. 976 (1969)). While noting the fact-dependent nature of that inquiry, the Court identified several factors (in a non-exhaustive fashion) that might be relevant in the merger context that was at issue in *Basic*. *Id.* at 239.

As it did in *Basic*, this Court should accord "due deference" to the SEC's views, as conveyed in this brief, on the proper materiality inquiry. 485 U.S. at 239 n.16. In this context, involving similarly uncertain information about potential adverse effects of using a company's drug, materiality may depend on multiple factors. With respect to the likelihood that the adverse-effect information will affect the drug's prospects, a court can consider the source of the reported adverse event (*Good Pharmacovigilance Practices* 4-5); the rate and severity of the adverse event; the potential benefit the drug provides; the availability of alternate therapies; whether the drug is new and has received FDA approval after clinical investigation (*Carter-Wallace*, 220 F.3d at 42); and the plausibility of a causal link (based on many of the factors FDA considers, see pp. 19-20, *supra*, such as temporal relationship and prior studies). With respect to the importance of the drug's success to the company's overall financial outlook, a court can consider the proportion of the company's current and expected revenues/profits from the drug, as well as the extent of any drop in stock price following disclosure of the omitted information. See, *e.g.*, *Hillson Partners, Ltd.* v. *Adage, Inc.*, 42 F.3d 204, 219 (4th Cir. 1994) (deeming omissions immaterial where financial impact on company would be negligible if prediction did not come true); *Ganino* v. *Citizens Util. Co.*, 228 F.3d 154, 162-63, 67 (2d Cir. 2000) (taking into account market movement upon disclosure along with other indicia). These factors are only illustrative, and

"[n]o particular event or factor * * * need be either necessary or sufficient by itself to render [such information] material." *Basic*, 485 U.S. at 239.

Application of *Basic*'s materiality standard in light of the aforementioned factors therefore would sometimes permit a company to withhold adverse drug information. For example, a company could reasonably conclude that a single report of an adverse event from an anonymous user, or a dozen reports of a dozen different adverse events, would not be important to a reasonable investor for a widely used drug that had undergone rigorous premarket testing and FDA review and approval. Even if the reports of an adverse effect were more numerous or reliable, a company could reasonably conclude that they were not material if the effect was minor and transient relative to the drug's benefit and the drug sales did not contribute meaningfully to the company's revenues. The choice that petitioners offer the Court—adopt a statistical significance threshold or force companies to disclose every report of an adverse effect to stave off liability—is ultimately a false one.[7]

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[7] The PSLRA's provisions governing private actions, including the heightened pleading requirements for misleading statements and omissions (15 U.S.C. 78u-4(b)(1)), and the safe harbor for forward-looking statements (15 U.S.C. 78u-5), establish additional mechanisms for weeding out meritless private securities-fraud lawsuits without unnecessarily impinging on the government's enforcement efforts. Moreover, under the judicially crafted "bespeaks caution" doctrine, predictive statements are not actionable if they are accompanied by specific cautionary language. *E.g.*, *Edward J. Goodman Life Income Trust* v. *Jabil Circuit, Inc.*, 594 F.3d 783, 796 (11th Cir. 2010). These protections provide further filtering above and beyond *Basic*.

4. Respondents' allegations regarding the omitted information about Zicam use and anosmia are sufficient to plead materiality under Basic

Applying *Basic*'s standard in light of the factors discussed above, respondents' complaint adequately alleges materiality.

First, much of the information associating Zicam use with anosmia was provided by experts in the field. Three different medical researchers and physicians communicated their concerns about a link between Zicam use and anosmia. As conveyed to Matrixx, those concerns were based in part on the experts' treatment and observation of at least a dozen patients who experienced anosmia after using Zicam, and in part on published studies establishing a link between anosmia and another zinc compound.

Second, drug-induced anosmia is a relatively serious side effect. J.A. 274a n.2. Given that Zicam is a medication that claims to lessen the duration of cold symptoms and that many alternate remedies are available, consumer awareness of even a low probability of developing anosmia could have significantly reduced Zicam's sales.

Third, Zicam did not have a new drug application approved by FDA. J.A. 269a. Clinical trials sufficient for FDA approval can take years to complete, may involve thousands of human subjects, and systematically evaluate a drug's benefits and risks. See, *e.g.*, *Abigail Alliance* v. *Von Eschenbach*, 495 F.3d 695, 697-698 (D.C. Cir. 2007), cert. denied, 128 S. Ct. 1069 (2008). A reasonable investor could attach greater significance to adverse event reports concerning a new drug (like Zicam) that has not undergone FDA review and ap-

proval than to similar reports concerning a drug for which a larger body of data was available.[8]

Fourth, several of the facts alleged—independent of the expert assessments shared with Matrixx—suggest a plausible causal link between Zicam use and anosmia. According to the complaint, at least some users suffered a severe burning sensation and loss of smell immediately after intranasal application of Zicam. J.A. 69a-70a (¶ 28). Those allegations, combined with the published studies linking anosmia to another zinc compound, support the notion that consumers (and possibly regulators) would consider a causal connection plausible.

Fifth, the fact that Matrixx's stock fell 23.8% the day after the *Good Morning America* story supports the conclusion that the omitted information would have been important to a reasonable investor. J.A. 81a (¶ 43). The strong correlation between Zicam's success and Matrixx's financial prospects is unsurprising given that Zicam constituted 70% of Matrixx's total sales at the time. J.A. 60a (¶ 2). Under petitioners' extreme view, by contrast, a trier of fact would not even be allowed to consider whether a reasonable investor would have attached significance to information that, when released to the public, demonstrably affected actual investor behavior.

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[8] Citing a press release, petitioners state that "[p]rior to the events at issue here, Matrixx conducted two published double-blind, placebo-controlled, randomized clinical studies of the intranasal application of zinc gluconate." Pet. Br. 5 (citing J.A. 193a-194a). Matrixx effectively contradicted that press release (and undercut the probative value of those two studies), however, when it subsequently declared that a panel of scientists convened "to review current information on smell disorders" had concluded that "there is insufficient scientific evidence at this time to determine if zinc gluconate, when used as recommended, affects a person's ability to smell." J.A. 82a (¶¶ 45-46).

B. Respondents Adequately Alleged That Petitioners Acted With Scienter

The PSLRA requires a private plaintiff in a Section 10(b) suit to "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. 78u-4(b)(2). Scienter, the state of mind required under Section 10(b), is "a mental state embracing intent to deceive, manipulate, or defraud." *Ernst & Ernst* v. *Hochfelder*, 425 U.S. 185, 193 n.12 (1976). "Every Court of Appeals that has considered the issue has held" that scienter may be proven "by showing that the defendant acted intentionally or recklessly." *Tellabs, Inc.* v. *Makor Issues & Rights, Ltd.*, 551 U.S. 308, 318 n.3 (2007). A "strong inference" of scienter is an inference "cogent and at least as compelling as any opposing inference of nonfraudulent intent." *Id.* at 314.

Respondents satisfied the PSLRA standard. In addition to the facts discussed above (pp. 30-31, *supra*), Matrixx prevented Dr. Jafek from using Zicam's name in the presentation of his case study on anosmia, suggesting strongly that Matrixx was aware of the potential damage that such a disclosure could do to Zicam's prospects. Matrixx's failure to disclose a pending anosmia-related lawsuit while noting the material risks of even a meritless product-liability claim further suggests deceptive intent. J.A. 75a-76a (¶ 35). Finally, although Matrixx publicly stated that reports of anosmia were "completely unfounded" because "the safety and efficacy of zinc gluconate" were "well established," J.A. 77a-78a (¶ 38), it shortly thereafter admitted that a panel of scientists it had convened had concluded that "there is insufficient scientific evidence at this time to determine if zinc gluconate, when used as recommended, affects a

person's ability to smell," J.A. 82a (¶¶ 45-46). Taken together, the facts alleged in respondents' complaint establish the requisite "strong inference that the defendant acted with the required state of mind." 15 U.S.C. 78u-4(b)(2).

CONCLUSION

The judgment of the court of appeals should be affirmed.

Respectfully submitted.

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APPENDIX

1. 15 U.S.C. 78j provides in pertinent part:

Manipulative and deceptive devices

It shall be unlawful for any person, directly or indirectly, by the use of any means or instrumentality of interstate commerce or of the mails, or of any facility of any national securities exchange—

* * * * *

(b) To use or employ, in connection with the purchase or sale of any security registered on a national securities exchange or any security not so registered, or any securities-based swap agreement (as defined in section 206B of the Gramm-Leach-Bliley Act), any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the Commission may prescribe as necessary or appropriate in the public interest or for the protection of investors.

2. 15 U.S.C. 78u-4 provides in pertinent part:

Private securities litigation

* * * * *

(b) Requirements for securities fraud actions

(1) Misleading statements and omissions

In any private action arising under this chapter in which the plaintiff alleges that the defendant—

(A) made an untrue statement of a material fact; or

(B) omitted to state a material fact necessary in order to make the statements made, in the light of the circumstances in which they were made, not misleading;

the complaint shall specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed.

(2) Required state of mind

In any private action arising under this chapter in which the plaintiff may recover money damages only on proof that the defendant acted with a particular state of mind, the complaint shall, with respect to each act or omission alleged to violate this chapter, state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind.

3. 17 C.F.R. § 240.10b-5 provides:

Employment of manipulative and deceptive devices.

It shall be unlawful for any person, directly or indirectly, by the use of any means or instrumentality of interstate commerce, or of the mails or of any facility of any national securities exchange,

(a) To employ any device, scheme, or artifice to defraud,

(b) To make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading, or

(c) To engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person,

in connection with the purchase or sale of any security.

AMICUS CURIAE BRIEF

No. 09-1156

In the Supreme Court of the United States

MATRIXX INITIATIVES, INC., ET AL.,
Petitioners,

v.

JAMES SIRACUSANO, ET AL.,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

BRIEF OF AARP AND NORTH AMERICAN SECURITIES ADMINISTRATORS ASSOCIATION, INC., AS *AMICI CURIAE* IN SUPPORT OF RESPONDENTS

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INTEREST OF *AMICI CURIAE*[1]

AARP is a non-partisan, non-profit organization dedicated to representing the needs and interests of people age fifty and older. AARP is greatly concerned about fraudulent, deceptive and unfair business practices, many of which disproportionately harm older people. AARP thus supports laws and public policies designed to protect older people from such business practices and to preserve the legal means for them to seek redress. Among these activities, AARP advocates for improved access to the civil justice system and supports the availability of the full range of enforcement tools, including class actions.

A significant percentage of the age fifty and older population in general tends to compose the investing public in the United States markets, and AARP members in particular tend to be investors in those markets. Older persons are frequent targets of financial fraud because they often have significant assets and they look for investment opportunities that will supplement Social Security and other sources of retirement income. As a result, AARP has elevated the need to combat securities fraud and made this issue a high priority. The Association has regularly commented on legislative and regulatory proposals that address investment fraud, filed

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1 In accordance with this Court's Rule 37.6, no party's counsel wrote this brief in whole or in part and no person other than amici or their counsel made a monetary contribution intended to fund the preparation or submission of the brief. The parties' letters consenting to the filing of this brief have been lodged with the Clerk of the Court.

amicus briefs in cases involving the securities laws, and opposed legislative efforts to limit the remedies of defrauded investors.

The North American Securities Administrators Association, Inc. ("NASAA") is the non-profit association of state, provincial, and territorial securities regulators in the United States, Canada, and Mexico. It has sixty-seven (67) members, including the securities regulators in all fifty (50) states, the District of Columbia, Puerto Rico, and the U.S. Virgin islands. Formed in 1919, NASAA is the oldest international organization devoted to protecting investors from fraud and abuse in the offer and sale of securities.

NASAA's members are responsible for regulating securities transactions under state law, and their principal activities include registering local securities offerings; licensing the brokers and investment advisers who sell securities or provide investment advice; and initiating enforcement actions to address fraud and other misconduct. They are intimately familiar with the investment offerings and sales abuses confronting their state residents on a daily basis, including problems posed by public misrepresentations in the media, offering documents and SEC filings.

NASAA supports all of its members' activities and it appears as *amicus curiae* in important cases involving securities regulation and investor protection. Recognizing that private actions are an essential complement to governmental enforcement

of the securities laws, NASAA and its members also support the rights of investors to seek redress in court for investment-related fraud and abuse. NASAA and its members have an interest in this appeal because it will profoundly affect the standard to which investors are held at the pleading stage.

The resolution of this case will have a significant impact on the integrity of the securities markets and the remediation of securities fraud in those markets. This is of particular concern at this time, both to AARP and NASAA, given the entry of many first-time investors into the market and the responsibility for retirement investing that pensioners have had to assume as a result of the shift in the retirement plan paradigm from defined benefit pension plans (under which employers bear the risk of loss) to defined contribution pension plans (under which plan participants bear the risk of loss).

AARP and NASAA believe that the Ninth Circuit properly held that respondents have satisfied all necessary pleading requirements, including those with respect to the question of materiality. Because respondents and other *amici* will have thoroughly addressed that point, this brief focuses primarily on the issue of scienter.

SUMMARY OF ARGUMENT

The Ninth Circuit's approach to the scienter requirement in this securities fraud action is well grounded in this Court's precedent. The conclusion that the actions of petitioner Matrixx Initiatives, Inc.

("Matrixx"), as alleged in the complaint, give rise to a strong inference of scienter follows naturally from this Court's decision in *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308 (2007). Allegations that Matrixx was aware of anecdotal and scientific evidence raising questions about a Zicam-anosmia link are sufficiently particularized to satisfy the pleading standard for securities fraud, and the assertion that the company sought to hide or refute this evidence with deliberate recklessness is at least as compelling as any plausible nonculpable explanation.

An analysis of evident inferences presents the following picture: Matrixx was on notice about consumer complaints of Zicam users developing anosmia as early as 1999, and in 2002 Matrixx reached out to independent researchers to discuss the potential dangers. Matrixx's own scientists could not disprove the existence of the Zicam-anosmia link, yet Matrixx refused to commission additional outside research. Then, in reacting to widespread media coverage of a Zicam-anosmia link, Matrixx issued intentionally misleading press releases that falsely implied to readers that two prior studies had tested for anosmia and returned negative results. Lastly, Matrixx's discussion of potential product liability litigation risks in its Securities and Exchange Commission ("SEC") Form 10-Q filings omitted the significant fact that an anosmia related lawsuit had already been filed against the company.

Contrary to the theory that petitioners and their *amici* attempt to advance, *Tellabs* does not require the inference of scienter to be irrefutable, or

for the court to determine and rule on which inference is most cogent. Rather, a court must allow a case to proceed beyond a Rule 12(b)(6) motion if a reasonable person, when viewing the complaint in its entirety and taking all facts alleged as true, would deem the inference of scienter cogent and at least as compelling as any plausible opposing inferences that could be drawn from the facts alleged. The Ninth Circuit correctly applied this standard in reversing the district court's judgment of dismissal in this case.

ARGUMENT

I. THE COMPLAINT SUPPORTS A FINDING OF A "STRONG INFERENCE" OF SCIENTER WHERE PETITIONERS HAD DIRECT KNOWLEDGE OF THE ZICAM-ANOSMIA LINK.

The Private Securities Litigation Reform Act (the "PSLRA"), 109 Stat. 737, requires a plaintiff in a private securities fraud action to plead facts that show the defendant acted with scienter.

This Court outlined the proper method for applying the PSLRA standard on a Federal Rule of Civil Procedure 12(b)(6) motion to dismiss in *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308 (2007). First, as with any 12(b)(6) motion, courts must accept all factual allegations in the complaint as true. *Id.* at 322; *see also Leatherman v. Tarrant County Narcotics Intelligence & Coordination Unit*, 507 U.S. 163, 164 (1993).

Second, courts must consider the complaint in its entirety, as well as other sources courts ordinarily examine when ruling on Rule 12(b)(6) motions. *Tellabs*, 551 U.S. at 322-23. The *Tellabs* analysis requires courts to "assess all the allegations holistically," rather than picking the complaint apart paragraph by paragraph. *Id.* at 326. The inquiry is "whether *all* of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard." *Id.* at 323 (emphasis in original). This inquiry is necessarily fact-intensive.

Third, in determining whether the pleaded facts give rise to a "strong inference" of scienter, the court must consider any "*plausible* nonculpable explanations" for the defendant's conduct in relation to the inferences favoring the plaintiff. *Id.* at 323-24 (emphasis added). A complaint will survive a motion to dismiss so long as the inference that the defendant acted with scienter is "cogent and compelling" or "strong in light of other explanations." *Id.* at 324. The court, however, emphasized that the inference of scienter need not be irrefutable, only that the inference must be cogent enough for a reasonable person to find it "at least as compelling" as any plausible opposing inference that could be drawn from the facts alleged in the complaint. *Id.*

Petitioners' *amicus* the Washington Legal Foundation ("WLF") argues for reversal based on their assertion that the Ninth Circuit "utterly failed" to consider competing inferences. Brief of Washington Legal Foundation as Amicus Curiae in

Support of Petitioners at 20-26, Matrixx Init., Inc., et al. v. Siracusano, No. 09-1156 (U.S. filed Aug. 27, 2010) [hereinafter WLF Brief]. This assertion is plainly incorrect. WLF also argues that the "most cogent" rationale for Matrixx's decision to withhold, and even attempt to contradict, any evidence of a Zicam-anosmia link is that Matrixx believed the information was immaterial. Not only does this argument misrepresent the *Tellabs* standard, the facts as alleged in the complaint tell an entirely different story.

A. The Appellate Court Properly Applied This Court's Decision in *Tellabs*.

Contrary to petitioners' assertion, the Ninth Circuit's opinion was completely in keeping with this Court's ruling in *Tellabs*. After a careful and attentive analysis of all factual allegations, the Ninth Circuit properly concluded that the complaint as a whole created a strong inference that petitioners acted with scienter in failing to disclose evidence of the Zicam-anosmia link.

Carefully reviewing the particulars of the complaint, the court noted the salient aspects of plaintiffs' allegations: in 1999, Matrixx began to receive complaints of anosmia from Zicam users; in 2002, concern about a potential Zicam-anosmia link led Matrixx's Director of Research and Development's to confer with an outside researcher about a complaining patient and subsequently asked that patient to participate in Zicam studies investigating the anosmia link; in September 2003,

Matrixx knew that a group of medical rhinologic researchers were presenting findings regarding no fewer than ten patients who had developed anosmia after Zicam use, and Matrixx withheld its consent from the presenters to use Matrixx's or Zicam's name in the presentation; in October 2003, Matrixx touted Zicam's potential for growth and profitability in a press release and an earnings conference call; later that month, a Zicam user filed a lawsuit against Matrixx alleging anosmia; and in November 2003, Matrixx neglected to disclose the lawsuit in the required "Quantitative and Qualitative Disclosures About Market Risk" section[2] of its Form 10-Q filing.[3] More Zicam users filed lawsuits against Matrixx in December 2003 and January 2004.

On February 2, 2004, Matrixx issued a press release responding to the January 30, 2004, Dow Jones report that the FDA was investigating Zicam and anosmia. Matrixx's press release called the report "completely unfounded and misleading" and asserted that clinical trials had established the safety of zinc gluconate. On February 6, 2004, *Good Morning America* reported on the possible link between Zicam and anosmia, and Matrixx issued another press release asserting that zinc gluconate's safety was well established in clinical trials, even though it was subsequently reported that Matrixx

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[2] *See* Form 10-Q, Item 3, 17 C.F.R § 249.308a; SEC Reg. S-K, Item 305, 17 C.F.R. § 229.305.

[3] Matrixx Initiatives, Inc., Nov. 12, 2003, Form 10-Q (filed Nov. 12, 2003), available at http://www.matrixxinc.com/secfiling.cfm?filingID=950153-03-2260.

had not conducted any studies relevant to that possible link. In a February 27, 2004, 8-K filing[4] with the SEC, Matrixx stated that it had convened a panel of physicians and scientists to review the information and asserted that there was insufficient evidence to determine whether zinc gluconate affected the sense of smell. On March 4, 2004, a news article reported that Matrixx would begin studies to determine if Zicam caused anosmia.

The Ninth Circuit reviewed the history of Matrixx's misleading statements about Zicam as alleged in the complaint, noting that Matrixx's first allegedly misleading statement was its October 22, 2003, press release, announcing the 163% net sales increase, attributed to Zicam, and stating that the Zicam brand was "poised for growth." The second statement was the conference call on October 23, 2003, again attributing the company's positive results to Zicam and projecting further growth. By the time of the press release and the conference call, several telephone conferences had been held between Matrixx personnel and outside researchers who, based upon patient complaints, had expressed concern about the possible link between Zicam and anosmia. Also by that time the first products liability lawsuit against Matrixx had been filed. At the time the company made these statements, Matrixx was aware of at least fourteen complaints regarding Zicam and anosmia. It was also alleged that

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[4] Matrixx Initiatives, Inc., Feb. 27, 2004, Form 8-K (filed Feb. 27, 2004), available at http://www.matrixxinc.com/secfiling.cfm?filingID=950153-04-484

Matrixx had acknowledged that it "had received customer complaints of loss of smell as early as 1999." The complaint also alleged that the November 12, 2003, Form 10-Q was misleading because it spoke of the risk of product liability actions against the company without revealing that a lawsuit had already been filed.

After this lengthy analysis of the facts alleged, the court went on to state:

> Viewing the CAC [consolidated amended complaint] as a whole, the inference of scienter is "cogent and at least as compelling" as any "plausible nonculpable explanation[]" for Appellees' conduct. Withholding reports of adverse effects of and lawsuits concerning the product responsible for the company's remarkable sales increase is "an extreme departure from the standards of ordinary care" and "presents a danger of misleading buyers or sellers." (citation omitted). We therefore conclude that the inference that Appellees withheld the information intentionally or with deliberate recklessness is at least as compelling as the inference that Appellees withheld the information innocently.

Siracusano v. Matrixx Initiatives, Inc., 585 F.3d 1167, 1183 (9th Cir. 2009) (quotations and most omissions in original).

In order to maintain market integrity, there must be full disclosure of material information to the investing public. This Court in *Basic v. Levinson*, 485 U.S. 224 (1988), reiterated that, "[i]n an open and developed market, the dissemination of material misrepresentations or withholding of material information typically affects the price of the stock as a reflection of its value." 485 U.S. at 244 (citing *Peil v. Speiser*, 806 F.2d 1154, 1161 (3d Cir. 1986)). This reasoning was recently adopted by the Seventh Circuit, wherein the Court explained: "[w]hen someone makes a false (or true) statement that adds to the supply of available information, the news passes to each investor *through the price of the stock.*" *Schleicher v. Wendt*, 618 F.3d 679, 682 (7th Cir. 2010) (emphasis in the original). The movement in the price of Matrixx stock following public information is a strong indication of the material nature of the information.

On January 30, 2004, Dow Jones Newswires reported that the FDA was looking into complaints of a Matrixx product that "may be causing some users to lose their sense of smell." Following the news report, Matrixx stock dropped 11.66%, from $13.55 per share on Friday, January 30, 2004, to $11.97 per share on Monday, February 2, 2004. Matrixx countered the report by issuing a press release asserting that any statements linking Zicam to anosmia are "completely unfounded and misleading." Following Matrixx's press release, the stock rose 11.9518% to $13.40, on February 3, 2004. On February 6, 2004, the television program *Good Morning America* discussed the following: a consumer who used Zicam lost her sense of smell;

the Dr. Bruce Jafek study; and the fact that four lawsuits had been filed against Zicam alleging anosmia. Following this news report, Matrixx issued another denial of any link between Zicam and anosmia. Matrixx's denial could not undo the disclosures made by Dr. Jafek, and the stock price dropped 23.8% the following day on unusually heavy trading, falling from $13.05 per share to $9.94 per share. It is evident from the trading volume and significantly high price fluctuations that the reasonable investor was paying attention to the news concerning the safety of Zicam. Consequently, this information was material in the decision to buy and sell the stock.

Matrixx's brief references cases for the proposition that drug companies need not disclose isolated reports of illnesses until those reports provide statistically significant evidence that their drugs caused the adverse effects. While it may be true that isolated reports of illnesses may not always require drug companies to issue public statements, this is not the scenario at play in the present case. Pharmaceutical companies comply with testing requirements and go through trials as required by the FDA. Consequently, if a report of an illness is received, the drug company can evaluate the report against the data and results of its tests and trials in order to determine whether the report has any merit and whether it is significant. Companies have in fact withdrawn drugs from the market where only a few adverse effect reports where received, depending on the nature of the reports and the scientific

information that the company had.[5] The determination of whether to report adverse effects to the general public cannot be properly made by a company that has not conducted adequate safety tests.

In the present case, Matrixx failed to conduct studies for anosmia, notwithstanding the fact that its product was being sprayed and applied inside the nose. Consequently, when Matrixx received reports from reputable medical professionals with expertise in olfactory issues, it should have realized that the reports were indeed significant, particularly since there was not a shred of research on Matrixx's part to show that the doctors' findings were incorrect. The fact that Matrixx threatened Dr. Jafek when he asked for permission to use the Zicam name in his presentation about Zicam is a good indication that Matrixx believed the information to be material. If Dr. Jafek's findings were insignificant, Matrixx would not have insisted on removal of the Zicam name. Similarly, if Matrixx believed that a reasonable investor would not be interested in whether some people lost their sense of smell, it would not have gone through great lengths to issue its own releases in an attempt to persuade investors to the contrary.

WLF argues that a reversal is warranted because the Ninth Circuit failed to engage in a "comparative analysis" of the competing inferences raised by the facts in the complaint. It also argues

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[5] For example, on February 28, 2005, the multiple-sclerosis drug Tysabri was withdrawn when two patients contracted progressive multifocal leukoencephalopathyits.

that the most cogent inference from the facts alleged is that Matrixx withheld certain information because it did not consider the information to be material. Neither assertion is persuasive, as petitioners misconstrue the *Tellabs* standard. The court is not required to determine which inference is the "most cogent"; rather, the court must have an eye to whether the scienter inference is just as compelling as competing inferences.

Contrary to petitioners' position, the Ninth Circuit's opinion emphasizes this balance by considering petitioners' actions during the class period as a whole and determining that a strong, cogent, compelling inference of scienter exists. In so finding, the Ninth Circuit was faithful to *Tellabs,* and its decision should stand.

B. Matrixx's Post-Class Period Admission Contradicted Its Earlier Press Releases and It Supports an Inference of Scienter.

The heightened pleading standard expressed in the PSLRA has given rise to the need in the various courts of appeals to define the pleading criteria that a plaintiff must meet in order to comply with the statutory requirements to effectively plead a securities fraud case. Indeed, the Ninth Circuit has held that in order to meet the revised pleading standard a plaintiff must allege facts which show the defendant acted with intention or deliberate

recklessness. *See Ronconi v. Larkin*, 253 F.3d 423, 432 (9th Cir. 2001).

Matrixx's February 27, 2004, Form 8-K filing with the SEC contains a compelling instance of deliberate recklessness, if not intentional misconduct, from which a strong inference of scienter arises. The filing contains a post-class period admission that a two-day, specially convened scientific panel concluded "there was insufficient evidence to determine whether zinc gluconate affected the sense of smell." *Siracusano*, 585 F.3d at 1175. Further, it was reported that Matrixx's own scientists "don't know if their nasal gel could cause loss of smell." *Id.* These revelations lay a basis for the contention that Matrixx had reason to believe in the possibility of the Zicam-anosmia link that had been alleged by outside patients and researchers, and that the company clearly had enough data concerning the causation link to alert Matrixx investors. Thus, Matrixx's initiative to make a public refutation of the theory of a link between its Zicam product and the anosmia condition instead of disclosing to its investors that there was an ongoing scientific inquiry into the possibility of the Zicam-anosmia link was made with deliberate recklessness sufficient to support a compelling inference of scienter.

In contending for dismissal of plaintiffs' complaint, Matrixx asserts that this 8-K admission did not contradict the company's earlier press releases, which publicly claimed absolutely no link between Zicam and anosmia. This assertion is specious at first glance, but in any case it proves

wholly inaccurate upon examination. Matrixx's scientists did not repudiate the existence of a Zicam-anosmia link. Rather, they announced that "there was insufficient scientific evidence . . . to determine if zinc gluconate . . . affects a person's ability to smell," indicating that they simply could not declare an answer supporting or disproving the link. *Id.* But if Matrixx's own scientists could not determine "whether" Zicam causes anosmia, they are actually acknowledging that they could not determine "whether or not" Zicam causes anosmia. It is beyond argument that implicit in the company's tiptoeing around the issue in public statements was the potential existence of a Zicam-anosmia link, a potential that Matrixx labored to ignore or misrepresent. In the midst of this scenario, Matrixx continued to publicly deny the existence of the Zicam-anosmia link. Matrixx's knowledge and actions constituted deliberate recklessness for purposes of pleading scienter.

Matrixx's conduct reveals a deliberate and concerted effort to obfuscate the company's historic lack of initiative to determine whether there existed a Zicam-anosmia causation link. The specialized nature of the scientific panel and the panel's inquiry results constituted "specific information," that should have been sufficient cause to arouse suspicion in Matrixx of a Zicam-anosmia link. The company's failure and refusal to so acknowledge, coupled with its misleading statements to the contrary, constitutes deliberate recklessness amounting to scienter.

C. Matrixx's February 2004 Press Releases Intentionally or Recklessly Implied That Studies Tested Specifically For A Link Between Zicam And Anosmia, Thereby Dispelling Any Such Connection.

Plaintiffs' factual allegations surrounding Matrixx's public denials of a Zicam-anosmia link, despite their knowledge of user complaints and ongoing scientific investigation in the medical community, including research specifically focused on the connection, support a strong inference of scienter on the part of the defendants. On February 2 and 6, 2004, Matrixx responded to reports linking Zicam to anosmia with press releases strongly denying any such link, and going so far as to vehemently insist that the reports were "completely unfounded and misleading." *Siracusano*, 585 F.3d at 1174. Indeed, the company's protests and the tenor of denials were themselves misleading, and crossed the line from innocent to deceptive.

Matrixx's press releases and public denouncement of the Zicam-anosmia link, despite the company's knowledge of consumer complaints, present a compelling instance of intentionally misleading the public, which gives rise to a strong inference of scienter. As early as 1999, Matrixx was aware of a potential Zicam-anosmia link when Dr. Alan Hirsch, the Neurological Director of the Smell & Taste Treatment and Research Foundation, called the Matrixx customer service line to request

information about the amount of zinc contained in Zicam's nasal gel. *Siracusano*, 585 F.3d at 1170. Hirsch, who had at least one patient who developed anosmia after using Zicam, was calling to discuss this patient and in the course of his conversation he informed Matrixx that independent studies indicated potential problems with the "intranasal application of zinc." *Id.* Dr. Hirsch offered to conduct his own study on the safety of Zicam, an offer which Matrixx officials declined. *Id.* Although the refusal of Dr. Hirsch's proposal does not alone implicate deception on the part of Matrixx, that response, taken in the context of the larger scenario of the company's avoidance of potentially damaging revelations about its product, suggests serious omissions in the realm of disclosure. The securities laws do not condone such an ostrich-like posture on the part of an issuer.

Moreover, in 2002, Matrixx's Vice President of Research and Development Timothy Clarot contacted Miriam Linschoten, Ph.D., at the University of Colorado Health Sciences Center regarding her treatment of a patient with loss of smell following the use of Zicam. *Id.* During the conversation with Dr. Linschoten, Clarot indicated that Matrixx had received similar consumer complaints dating back to 1999. *Id.* Dr. Linschoten used this conversation to inform Clarot about studies linking zinc sulfate to the loss of smell. *Id.* Clarot replied that Matrixx had not conducted any studies of its own. *Id.*

Petitioners and respective *amici* insist that Matrixx was simply acting prudently by waiting to discover the association, "if any", between Zicam and

anosmia. However, the allegations stated in the complaint clearly indicate that Matrixx was aware of the potential link through consumer complaints, communication with independent researchers, and the company's own scientific data. It can fairly be gleaned from the complaint that plaintiffs allege Matrixx's affirmative misstatements regarding consumer complaints and the "completely unfounded and misleading" nature of claims asserting a Zicam-anosmia link were made with the knowledge that the statements were outright false and that they were intended to mislead investors. Surely, by pleading these particulars plaintiffs have hurdled the scienter bar.

In this context, Matrixx knowingly released misleading statements denying the existence of the Zicam-anosmia link. It was Matrixx's public position that Zicam's safety and efficacy were "well established" in two prior trials, and the company protests that the press releases neither stated nor implied that the studies were designed to explore a causal link between Zicam and anosmia. Therefore, argues Matrixx, the February press releases were in no way designed to mislead the public regarding the Zicam-anosmia link. But the law under § 10(b) of the Securities Exchange Act, 15 U.S.C. § 78j(b), and Rule 10(b)-5, 17 C.F.R. § 240.10(b), promulgated thereunder, does not support such a microscopic analysis of the facts; instead it calls for a holistic examination of the company's conduct. *Tellabs*, 551 U.S. at 322-23. More significantly, the timing and context of Matrixx's denials paint a very different picture, one that deceptively purports to combat and contradict disclosures and extensive media coverage

of the existence of the Zicam-anosmia link. It can plainly be seen that the press releases denied the Zicam-anosmia link impliedly based on the results of the two prior trials. It can no less plainly be inferred that a reasonable investor would construe Matrixx's press releases to mean that the two prior Zicam trials had tested specifically for anosmia and made conclusions repudiating a connection between the product and the condition – a misapprehension, to be sure!

To the credit of plaintiffs' pleadings here, courts of appeals have held that even literally "true" statements can mislead investors when viewed in context. *See Operating Local 649 Annuity Trust Fund v. Smith Barney*, 595 F.3d 86, 92 (2d Cir. 2010) ("[t]he veracity of a statement or omission is measured not by its literal truth, but by its ability to accurately inform rather than mislead prospective buyers"); *In re Convergent Techs. Sec. Litig.*, 948 F.2d 507, 512 (9th Cir. 1991) ("[s]ome statements, although literally accurate, can become, through their context and manner of presentation, devices which mislead investors. For that reason, the disclosure required by the securities laws is measured not by literal truth, but by the ability of the material to accurately inform rather than mislead prospective buyers"); *McMahan & Co. v. Wherehouse Entm't, Inc.*, 900 F.2d 576, 579 (2d Cir. 1990) ([t]he central issue . . . is not whether the particular statements, taken separately, were literally true, but whether defendants' representations, taken together and in context, would have mislead a reasonable investor").

In this case Matrixx attempted to mitigate the damaging media coverage of the Zicam-anosmia link by circulating two press releases addressing the issue. Both press releases indicated that Zicam's safety and efficacy were well established in two prior trials, but the statements omitted mention of the fact that trials did not test specifically for anosmia. When analyzed in context, as the applicable law requires, it can be fairly and persuasively inferred that the press releases were designed to mislead the public. Inasmuch as the press releases were issued in response to media coverage of the Zicam-anosmia link and they were intended to assert Zicam's safety, by leading their audience to the impression that the prior studies specifically tested for anosmia – a patent falsehood. Matrixx's actions have met the scienter threshold.

In view of the allegations that as early as 1999 Matrixx had knowledge of a potential Zicam-anosmia link through consumer complaints and independent research, that through the February 2004 press releases Matrixx announced to the public that their studies indicated the lack of a Zicam-anosmia link, and that these press releases implied to readers that the studies had tested specifically for that link, when they had not, sufficient pleadings were before the court that, taken as true, tend to establish that Matrixx "published statements when they knew facts suggesting the statements were inaccurate or misleadingly incomplete," and even attempted to re-characterize the facts in an attempt to deceive investors. *Aldridge v. A.T. Cross Corp.*, 284 F.3d 72, 83 (1st Cir. 2002). No more is required

to leap the scienter pleading hurdle posed by § 10(b) and Rule 10(b)-5.

II. THE COMPLAINT SUPPORTS A FINDING OF A "STRONG INFERENCE" OF SCIENTER WHERE SEC RULES ESTABLISHING A DUTY OF DISCLOSURE WERE VIOLATED.

SEC Regulation S-K, 17 C.F.R. § 229.10 *et seq.*, establishes a duty to disclose pending lawsuits in SEC filings. Regulation S-K "requires companies to report pending litigation meeting certain criteria relating to materiality." *City of Philadelphia v. Fleming Cos.*, 264 F.3d 1245, 1266 (10th Cir. 2001). The regulation mandates company disclosure of pending lawsuits by stating:

> Describe briefly any material pending legal proceedings, other than ordinary routine litigation incidental to the business, to which the registrant or any of its subsidiaries is a party or of which any of their property is the subject. Include the name of the court or agency in which the proceedings are pending, the date instituted, the principal parties thereto, a description of the factual basis alleged to underlie the proceeding and the relief sought.

17 C.F.R. § 229.103. SEC guidance further explains that "[a] legal proceeding need only be reported in the 10-Q filed for the quarter in which it became a reportable event." Uniform and Integrated Reporting

Requirements, Securities Act Release No. 33-5949, 1978 WL 170913 at *27 (July 28, 1978).

Petitioners and respective *amici* argue that under the SEC reporting rules, Matrixx was not required to report the existing lawsuit against them until the following quarter. The Ninth Circuit found to the contrary, stating that the omission gave rise to an inference of scienter because "[w]ithholding reports of . . . lawsuits concerning the product responsible for the company's remarkable sales increase is an extreme departure from the standards of ordinary care and presents a danger of misleading buyers or sellers." *Siracusano*, 585 F.3d at 1183. With the Form 10-Q, Matrixx violated a significant body of case law that assigns a duty to speak completely on a subject once it has been addressed. In the present case, Matrixx engaged in an active deception when it alluded to potential lawsuits in its SEC filings, but failed to speak honestly and completely about the subject matter.

Even though Matrixx was not necessarily under an obligation to discuss the potential effect on its business of a product liability lawsuit, once it did speak on the subject, it opened the door to an obligation to say more, *i.e.*, to reveal that such a lawsuit had been filed against the company.[6]

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[6] Courts of appeals generally agree that "even when there is no duty to disclose something – *i.e.*, the company could keep silent – once the company addresses a subject it has the duty to speak fully and truthfully on the subject." *Ackerman v. Schwartz*, 947 F.2d 841, 848 (7th Cir. 1991) ("[u]nder Rule 10b-5, moreover, the lack of an independent duty does not excuse a material lie. A subject of a tender offer or merger bid has no

The first product liability lawsuit regarding the Zicam-anosmia link was filed against Matrixx on October 14, 2003. *Siracusano*, 585 F.3d at 1172 n.3. Less than one month later, Matrixx filed a form 10-Q with the SEC, which included information regarding the risks of product liability lawsuits. *Id.* at 1172. Aside from this language, Matrixx made no mention of the pending product liability litigation. *Id.* With the inclusion of information regarding litigation risks, Matrixx clearly alluded to the devastating effect a potential product liability suit, even one

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duty to issue a press release, but if it chooses to speak it must tell the truth about material issues"); *see also Caiola v. Citibank*, 295 F.3d 312, 331 (2d Cir. 2002) (holding that "the lack of an independent duty" to disclose its hedging strategy "is not, under such circumstances, a defense to Rule 10b-5 liability because upon choosing to speak, one must speak truthfully about material issues"); *Rubin v. Schottenstein, Zox & Dunn*, 143 F.3d 263, 267-68 (6th Cir. 1998) (even if an attorney representing the seller in a securities transaction does not have an "independent duty" to volunteer information to a prospective buyer, "he assumes a duty to provide complete and non-misleading information with respect to subjects on which he undertakes to speak"); *In re Polaroid Corp. Secs. Litig.*, 134 F. Supp. 2d 176 (D. Mass. 2001) ("[a] voluntary disclosure of information that a reasonable investor would consider material must be complete and accurate. This, however, does not mean that by revealing one fact about a product, one must reveal all others that, too, would be interesting, market-wise, but means only such others, if any, that are needed so that what was revealed would not be so incomplete as to mislead"); *see generally Semerenko v. Cendant Corp.*, 223 F.3d 165, 187 n.14 (3d Cir. 2000) ("[t]hough defendants who are neither fiduciaries nor insiders generally are not under a duty to disclose material information, they subject themselves to liability under §10(b) and Rule 10b-5 when they make affirmative misrepresentations.").

without merit, could have on their operations going forward.

It must be emphasized that the Form 10-Q filing risk disclosure discussion is intended to be informative and meaningful, rather than an exercise in hypothetical posturing. Congress provided for companies and their responsible executives a safe harbor from PSLRA liability, conditioned on respect for the public corporation disclosure process of which Form 10-Q and other required filings are a part. *See, e.g.*, H.R. CONF. REP. NO. 104-369, at 43 (1995), *reprinted in* 1995 U.S.C.C.A.N. 730, 742 [hereinafter H.R. REP. NO. 104-369].

Amici AARP and NASAA are compelled take to task one of Matrixx's *amici* on its argument that Matrixx's technical compliance with Regulation S-K relieves Matrixx from the inference of scienter that arises on account of the company's failure to disclose in its November 2003 10-Q filing the fact that the first product liability suit claiming a Zicam-anosmia link had been filed. *See* WLF brief, *supra*, at 20-26. While the argument may be technically accurate in noting that the disclosure of the product liability suit was not required under Regulation S-K until the subsequent 10-Q filing, if at all under that Regulation, in no respect does Matrixx's technical compliance with the regulation diminish the strength of the scienter inference to be drawn from the failure to complete the Risk Disclosure section of the 10-Q with a factual statement about the actual filing of such a suit.

The wide body of case law dictates that at that point, Matrixx was under a duty to speak truthfully and admit to investors that a products liability lawsuit had recently been filed against the company. Although Matrixx had the option to keep silent, its decision to disclose information regarding the dangers of product liability litigation opened it up to a duty to disclose the pending product liability lawsuit. This omission supports an inference of scienter because Matrixx deceived investors by manipulating material information.

Petitioners and respective *amici* insist that investors would not have been misled by the information on litigation risks contained in the November 2003 Form 10-Q. They maintain that this statement was simply general information; therefore, Matrixx was under no duty to speak of actual pending lawsuits because the Form 10-Q statements did not "boast" about Matrixx. This contention is mistaken and misconstrues the wide body of case law from the several courts of appeals that have addressed this issue.

First, the warnings on the dangers of potential product liability litigation appeared in the "Risk Disclosures" section of Matrixx's Form 10-Q filing. However, this section of the Form 10-Q is provided to state information intended to give meaningful guidance to investors. *See* SEC Reg. S-K Item 305, 17 C.F.R. § 229.305. Without warrant, petitioners trivialize the form and substance of Form 10-Q in their contention otherwise. A reasonable investor would pay special attention to the information contained in the section and would not

be likely to consider the language "general information."

Further, Matrixx's *amicus* argues that the company was not under any duty to disclose pending litigation because the "boilerplate" language made no "boasts," nor was it intended to paint Matrixx in a favorable light. WLF brief, *supra*, at 22. In its characterization of the Form 10-Q Risk Disclosure as "boilerplate," petitioners' a*micus* does a disservice to this Court and to petitioners. Congress left no doubt in the PSLRA that "boilerplate warnings will not suffice." H.R. REP. NO. 104-369, *supra*, at 43. The entire purchase of petitioners' *amicus*'s argument is thus lost as a consequence of its misconstruction of the purpose of the Risk Disclosure requirements in the form 10-Q. Petitioners' de-emphasis of the significance of the Form 10-Q Risk Disclosure section, too, while offering a rationalization, misses the point, and it does nothing to dispel the resulting inference of scienter. The courts of appeals have never required boastful language to trigger the duty to speak truthfully. *See Ackerman*, 947 F.2d at 848; *see generally McAuley v. IBM Corp.*, 165 F.3d 1038 (6th Cir. 1999). Rather, the requirement is simply that once the company speaks on a subject, it must speak sufficiently truthfully and adequately. Clever dancing around the point here drew the company across the line into deliberate recklessness. In these circumstances, once Matrixx initiated a declaration about "potential" product liability, the duty was triggered to disclose existing exposure to product liability lawsuits. *A fortiori* this obligation was incumbent upon Matrixx given the unique, one-product type company that characterizes Matrixx.

Matrixx's failure to disclose its pending lawsuits violated settled case law and it supports a strong inference of deception satisfying the scienter element of pleading securities fraud.

CONCLUSION

For all of the foregoing reasons, *amici* respectfully submit that the decision of the Ninth Circuit should be affirmed.

November 12, 2010 Respectfully Submitted

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AMICUS CURIAE BRIEF

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Supreme Court of the United States

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Petitioners,

v.

JAMES SIRACUSANO, *et al.*,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

BRIEF FOR THE ADVANCED MEDICAL TECHNOLOGY ASSOCIATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

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No. 09-1156

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On Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

BRIEF FOR THE ADVANCED MEDICAL TECHNOLOGY ASSOCIATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

INTEREST OF THE *AMICUS CURIAE* [1]

The Advanced Medical Technology Association ("AdvaMed") is the largest medical technology association in the world, representing more than 300 medical device, diagnostic, and health information system companies. AdvaMed's members manufac-

[1] The parties have filed letters with the Clerk of Court consenting to the filing of all amicus briefs. No counsel for any party to these proceedings authored this brief, in whole or in part. No other entity or person, aside from *amicus* AdvaMed and its counsel, made any monetary contribution for the preparation or submission of this brief.

ture 90 percent of the $75 billion in health care technology purchased annually in the United States and over 50 percent of the $175 billion in global sales in this most vital of markets.

The question presented concerns an issue of fundamental importance to AdvaMed's members and to all healthcare companies subject to the federal requirements for adverse event reporting, as well as investors, health care providers, and patients more generally. AdvaMed has a strong interest in ensuring that the federal securities laws are construed so as to require healthcare companies to disclose publicly meaningful and coherent information, instead of partial and anecdotal information that would more likely mislead and confuse investors, rather than assist them.

In the decision below, the Ninth Circuit rejected the majority view, endorsed by three courts of appeal and numerous district courts, that a company's non-disclosure of adverse event reports to investors will not form the basis for a claim under Section 10(b) of the Securities Exchange Act and SEC Rule 10b-5, unless such reports are statistically significant.

The Ninth Circuit's decision rests on an apparent misconception about the nature of the adverse event reporting system. Left in place, it would require AdvaMed's members to include statistically insignificant and substantively meaningless reports in their public disclosures that would expand the information available to investors and consumers without qualitatively improving it. AdvaMed submits this *amicus curiae* brief to assist the Court in considering (1) the nature and role of federal adverse event reporting; and (2) the proper impact of adverse event reports on scienter in Rule 10b-5 actions.

SUMMARY OF ARGUMENT

The Food and Drug Administration ("FDA") requires healthcare companies, and encourages medical professionals voluntarily, to submit to the agency any and all anecdotal reports tying the use of a medical device or a pharmaceutical product to an adverse event. Although each report is typically meaningless if evaluated on its own—because the reports do not purport to show any actual causal link between the product and the adverse event—the FDA believes that, in the aggregate, the reporting of enough of these events might evidence a statistically significant link between the use of the product and some adverse condition that would merit further investigation.

Prior to the Ninth Circuit's decision below, the lower courts had agreed that plaintiffs proceeding under Section 10(b) of the Securities Exchange Act and SEC Rule 10b-5 could not state a claim based solely on a company's non-disclosure of adverse event reports to investors, absent a statistically significant link between the company's product and the adverse events. Those decisions rested upon an appreciation that the FDA's adverse event reporting system provides far more noise, absent some kind of scientifically valid screen, than the reliable, material information suitable for disclosure to investors under the securities laws.

As explained in Petitioners' opening brief, adverse event reports thus should not be regarded as material, unless they are sufficient to demonstrate a statistically significant link between the product and the adverse event. AdvaMed submits, however, that the requirements for scienter under the securities laws, as elucidated by this Court's decision in

Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308 (2007), provide an even more compelling reason why the Ninth Circuit's decision was in error.

In *Tellabs*, the Court held that a strong inference of scienter "must be more than merely plausible or reasonable—it must be cogent and ***at least as compelling as any opposing inference*** of nonfraudulent intent." *Id.* at 314 (emphasis added). In view of the nature of the FDA's adverse event reporting system, it is perfectly ordinary as a matter of practice and appropriate as a matter of prudence for a healthcare company to exercise caution in making public disclosures to investors unless or until the data evidences a statistically significant link. Accordingly, as a matter of law, a plaintiff cannot meet his burden of pleading facts giving rise to a strong inference of scienter "as compelling as any opposing inference" by simply pointing to a company's non-disclosure to the market of scientifically meaningless adverse event reports.

In concluding that the mere "[w]ithholding [of] reports of adverse effects" supports a strong inference of scienter, regardless of the reports' statistical significance, the Ninth Circuit misapplied the controlling principles of *Tellabs* and the stiff pleading requirements imposed by Congress for securities fraud claims. A careful examination of the nature and role of adverse event reporting under the relevant federal regulations compellingly exposes the flaws in the Ninth Circuit's reasoning and demonstrates why the decision should be reversed.

1. Federal regulations require companies that manufacture drugs, medical devices, vaccines, and other products to submit adverse event reports—known as Medical Device Reports ("MDRs") in the

medical device industry—to the FDA. MDRs, like all adverse event reports, reflect unverified anecdotal information submitted in various ways to manufacturers by health professionals and product users.

Although potentially useful in the aggregate, adverse event reports are inherently unreliable and subject to numerous biases. *First*, MDRs make no attempt to rule out even obvious alternative causes (let alone mere chance), because the FDA encourages submission of adverse event reports even in doubtful situations, such as cases of user error. The FDA's reporting systems often generate voluminous but questionable information that precludes determinations of cause and effect. *Second*, adverse event reports often omit critical information such as the patient's underlying illnesses, medical history, and concomitant use of other products and therapies. *Third*, adverse publicity, including litigation-generated mass media attention, greatly influences—and often distorts—reporting of adverse events. Indeed, the potential for distortion is greatly magnified under passive surveillance systems, like the FDA's voluntary reporting regime for medical professionals, that are inherently prone to underreporting.

Recognizing the inherent limitations of adverse event reports, the FDA expressly disclaims using them to assess causation. At most, MDRs are individual data points—"signals" in FDA parlance—that can suggest a need for further inquiry. By themselves, they establish no medical or scientific facts. The FDA thus employs sophisticated statistical analyses of adverse events in its databases before drawing any conclusions about their significance, and it expects life sciences companies to do the same.

The FDA's skepticism of raw adverse event reports is shared by courts analyzing causation in civil cases. Numerous courts have held that the inherent flaws of adverse event reporting are too serious to allow their use to prove causation.

2. The nature of the FDA's adverse event system underscores why statistical significance is necessary before a court may draw any inference, much less a "strong" inference, that non-disclosure of adverse event reports to the investing public is probative of scienter. Three well-established principles of securities law demonstrate why statistical significance is an appropriate minimum threshold for scienter in cases involving alleged non-disclosure of adverse events to investors:

First, a court may infer scienter from the defendant's non-disclosure of information only if there is plausible reason to think that the defendant believes he or she has something to hide. A strong inference of scienter therefore may not reasonably be inferred when the defendant regards the undisclosed information as unreliable or inconclusive. *In re Carter-Wallace Sec. Litig.*, 150 F.3d 153 (2d Cir. 1998), and 220 F.3d 36 (2d Cir. 2000), and its progeny among the lower courts, properly hold that the mere receipt of inconclusive adverse event reports does not support a strong inference of scienter. A defendant cannot be deemed to know of, let alone intentionally or recklessly ignore, a causal link between its product and an adverse event where the reports have never established such a connection. Unless and until adverse event reports reach the level of statistical significance, the most plausible inference under *Tellabs* will always be that the defendant reasonably believes that, in the overall context of the product's

history and experience in the market, the existence of the reports did not call into question the product's safety. The Ninth Circuit's contrary decision, equating raw adverse event reports with "red flags" about product safety, misunderstands that the multifarious, and sometimes conflicting, reports amount to little more than background noise in a much broader setting of product usage, unless and until subjected to statistical analysis.

Second, scienter must turn on a defendant's knowledge at the time of an alleged misstatement. "Fraud-by-hindsight" is not actionable under the securities laws. The subsequent linkage of a product to an adverse event does not demonstrate prior intent to deceive. Abandoning statistical significance as a prerequisite to a securities fraud claim would effectively hold a life sciences company and its officers culpable for not predicting—based on unreliable and inconclusive adverse event reports—the later emergence of a *bona fide* safety issue. The statistical significance standard protects defendants from such *post hoc* critiques. Indeed, the Ninth Circuit's finding of a strong inference of scienter based on non-disclosure of statistically insignificant adverse event reports (and an FDA warning letter issued some five years after the class period), raises the untenable specter of fraud-by-hindsight.

Third, a defendant's decision to investigate adverse event reports before publicly disclosing them reflects prudence, not the intent to defraud. A company cannot determine the scientific implications of a series of adverse event reports without engaging in a sophisticated statistical analysis of these cumulative reports. The FDA recognizes this and thus advises life sciences companies to investigate such reports

carefully before drawing any conclusions. In direct conflict with that direction, the Ninth Circuit actually concluded that Petitioners' investigation supported an inference of scienter, treating such raw reports as indicia of causation. That was error.

3. Adopting the Ninth Circuit's indiscriminate approach to disclosure of unverified adverse event reports would adversely affect life science companies, investors, and patients. If affirmed, the Ninth Circuit's decision would push companies selling pharmaceuticals, biotechnology, and medical technology to disclose publicly every single adverse event report—amounting to potentially hundreds of thousands of reports annually—with little regard to the strength of the causal link. Under such a regime, companies would be forced to give their imprimatur to unverified and unreliable reports about their products, leading in some cases to artificially depressed stock prices and increased volatility, as confused investors seek to separate the true nuggets of value amidst a torrent of unreliable information. Disclosing such statistically insignificant adverse event reports would harm investors and consumers by distorting the information upon which they base critical investment and health care decisions.

While statistical significance alone may not establish the strong inference of scienter that *Tellabs* demands, the failure even to allege it should be grounds for dismissal. The decision below should be reversed.

ARGUMENT

The decision below rests upon a misunderstanding of the significance of adverse event reports for products distributed among tens of thousands, and

sometimes millions, of consumers throughout the country and the world. As discussed below, the FDA has long recognized that adverse event reports do not constitute reliable information upon which companies or consumers should base actual medical decisions until statistical significance suggests a pattern that merits investigation. Yet the Ninth Circuit held that adverse event reports alone, even if statistically insignificant, may create a factual question about liability under the federal securities laws.

Although the lower court misapplied the principles that govern the element of materiality, as explained in Petitioners' opening brief, the Ninth Circuit's holding on scienter is premised upon an even more drastic error. It assumes an inference of ***fraudulent*** intent to be equally appropriate to a benign inference when a healthcare company prudently follows FDA recommendations—and common sense—by evaluating the implications of reported adverse events through the lens of science before making a public statement.

In pleading securities fraud, plaintiffs must "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind," *i.e.*, scienter. 15 U.S.C. § 78u-4(b)(2).[2] "To qualify as 'strong' within the intendment of § 21D(b)(2) . . . an inference of scienter must be more than merely plausible or reasonable—it must be cogent and at least as compelling as any opposing inference." *Tellabs*, 551 U.S. at 314. A court shall deny a motion to dismiss "only if a reasonable person

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[2] Scienter is "a mental state embracing intent to deceive, manipulate, or defraud." *Tellabs*, 551 U.S. at 319 (quotation marks and citation omitted).

would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *Id.* at 324.

Even before *Tellabs*, the Second Circuit had long recognized that non-disclosure of statistically insignificant adverse event reports cannot give rise to a strong inference of scienter. *In re Carter-Wallace, Inc. Sec. Litig.*, 150 F.3d 153 (2d Cir. 1998) ("*Carter-Wallace I*"); *In re Carter-Wallace, Inc. Sec. Litig.*, 220 F.3d 36 (2d Cir. 2000) ("*Carter-Wallace II*"). Two other courts of appeals subsequently adopted this standard, *see N.J. Carpenters Pension & Annuity Funds v. Biogen IDEC Inc.*, 537 F.3d 35 (1st Cir. 2008); *Oran v. Stafford*, 226 F.3d 275 (3d Cir. 2000) (Alito, J.),[3] and numerous district courts agree.[4] These courts recognize that absent statistical significance, the far more plausible inference to be drawn from non-disclosure to the public is that the adverse event reports did not yet evidence a correlation, much less a causal connection, between the product and the events.

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[3] While *Oran* was decided on materiality grounds, the court's analysis would apply equally well to scienter. *Cf. Carter-Wallace II*, 220 F.3d at 41 ("Not only were the financial statements not materially misleading before the link [between the product and an adverse event] could be made, but any inference of scienter was negated as well.").

[4] *See, e.g., Plumbers and Pipefitters Local Union 719 Pension Fund v. Zimmer Holdings, Inc.*, 673 F. Supp. 2d 718, 742 (S.D. Ind. 2009); *In re Medtronic, Inc. Sec. Litig.*, 618 F. Supp. 2d 1016, 1026 (D. Minn. 2009); *Kairalla v. Advanced Med. Optics, Inc.*, 2008 WL 2879087, at *10-11 (C.D. Cal. June 6, 2008); *In re Intrabiotics Pharm., Inc. Sec. Litig.*, 2006 WL 2192109, at *13-14 (N.D. Cal. Aug. 1, 2006).

In expressly rejecting statistical significance as a prerequisite, the Ninth Circuit considered neither the nature of adverse event reports under the FDA's regulatory scheme nor the importance of statistical analysis in evaluating such reports. Yet statistical significance remains the appropriate threshold for determining whether a defendant's non-disclosure of adverse event reports to investors can support any inference of scienter, much less the strong one required by the securities laws.

I. ADVERSE EVENT REPORTS PROVIDE NO RELIABLE BASIS TO INFER CAUSATION.

A. The FDA Requires Manufacturers To Report All Adverse Events Regardless of Causation.

AdvaMed's members, and all medical device manufacturers, must submit MDRs to the FDA for all suspected adverse incidents. 21 U.S.C. § 360i(a)(1).[5] This reporting requirement, contained in 21 C.F.R. § 803.50(a), extends to more than 20,000 companies and covers almost 100,000 medical devices, from tongue depressors to artificial heart valves.[6]

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[5] This brief focuses on adverse event reporting requirements applicable to medical device companies. Substantially similar requirements apply to virtually all FDA-regulated products, including drugs and vaccines. *See, e.g.*, 21 C.F.R. § 314.80 (drugs); 21 C.F.R. § 600.80 (vaccines).

[6] HHS Office of Inspector General, *Adverse Event Reporting for Medical Devices* ("*Adverse Event Reporting*"), at 1 (Oct. 2009), *available at* http://oig.hhs.gov/oei/reports/oei-01-08-00110.pdf. All Web pages cited herein were last visited no earlier than August 23, 2010.

MDRs must be filed with the FDA without regard to the likelihood of causation. An "MDR Reportable Event" occurs whenever a manufacturer learns of anything "reasonably suggest[ing]" that its device: (1) "[m]ay have caused or contributed to a death or serious injury," or (2) experienced a non-injurious "malfunction" that "would be likely to cause or contribute to a death or serious injury" if it recurred. 21 C.F.R. § 803.50(a).[7] "Caused or contributed" is defined to include unknown and doubtful cases:

> Caused or contributed means that a death or serious injury was or ***may have*** been attributed to a medical device, or a medical device ***may have*** been a factor in the death or serious injury.

21 C.F.R. § 803.3 (emphasis added); *see Riegel v. Medtronic, Inc.*, 552 U.S. 312, 319 (2008) (citing 21 C.F.R. § 803.50(a)). MDRs are required even for "user error." 21 C.F.R. § 803.3. Filing an MDR in no way establishes that a device had anything to do with the reported event:

> A report or other information . . . is not necessarily an admission that the device . . . caused or contributed to the reportable event. [Manufacturers] do not have to admit and may deny that the report or information submitted . . . constitutes an admission that the device . . . caused or contributed to the reportable event.

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[7] Malfunction MDRs must be filed whenever "the chance of a death or serious injury . . . is ***not*** remote." FDA, Center for Devices & Radiological Health, *Medical Device Reporting for Manufacturers* ("*Medical Device Reporting*"), 1997 WL 33793806 § 2 (Mar. 1, 1997). For malfunctions, there is "no[] need to assess the likelihood that a malfunction will recur," as recurrence is "presume[d]." *Id.*

21 C.F.R. § 803.16; *see* FDA, *Medical Device Reporting* § 3 (definition of "Disclaimers").[8]

Only two circumstances are exempt from reporting: (1) if the supposed event did not happen at all, and (2) if the event involves another manufacturer's device. FDA, *Medical Device Reporting* § 2.[9]

B. The FDA Recognizes that Adverse Event Reporting Is Subject to Significant Statistical Biases and Lacks Scientific Validity.

Not surprisingly, the FDA has long recognized the limitations of adverse event reporting for medical devices and drugs, and it readily acknowledges that these limitations preclude causation assessment:

> 1. For any given [reported] case, there is no certainty that the suspected drug caused the [adverse event]. This is because physicians and

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[8] The FDA intentionally chose more reports over better ones. As the Tenth Circuit has explained: "FDA reiterated the need for an expansive reporting system and adopted regulations that require manufacturers to file an MDR if they become aware of information suggesting that a device ***may*** have caused or contributed to a death or serious injury rather than the more limited language proposed that would have required manufacturers to file an MDR only in cases where they receive information suggesting that a device ***has*** caused or contributed to a death or serious injury." *TMJ Implants, Inc. v. U.S. Dept. of Health & Human Servs.*, 584 F.3d 1290, 1295 (10th Cir. 2009) (citing FDA regulation).

[9] A similarly broad reporting requirement exists for prescription drugs. Drug manufacturers must make reports to the FDA about "[a]ny adverse event associated with the use of a drug in humans, whether or not considered drug related." *Wyeth v. Levine*, 129 S. Ct. 1187, 1210 (2009) (quoting 21 C.F.R. §§ 314.80(a), (c), (j)).

> consumers are encouraged to report all suspected [adverse events], not just those that are already known to be caused by the drug. The adverse event may have been related to an underlying disease for which the drug was given, to other concomitant drugs, or may have occurred by chance at the same time the suspect drug was administered.
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> 2. Accumulated [adverse events] may not be used to calculate incidences or estimates of drug risk. Numbers from these data should be carefully interpreted as reporting rates and not occurrence or incidence rates.

FDA, Center for Drug Evaluation and Research, *Annual Adverse Event Drug Experience Report: 1996* 2 (Oct. 30, 1997).[10]

The FDA's current guidance on its Web site candidly advises that adverse event reports lack statistical validity:

> [T]here is no certainty that the reported event was actually due to the product. FDA does not require that a causal relationship between a product and event be proven, and reports do not always contain enough detail to properly evaluate an event. Further, FDA does not receive all adverse event reports that occur with a product. Many factors can influence whether or not an event will be reported, such as the time a product has been marketed and publicity about an event. Therefore, [adverse event reports] can-

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[10] *Available at* http://druganddevicelaw.net/Annual%20Adverse%20drug%20experience%20report%201996.pdf.

> not be used to calculate the incidence of an adverse event in the U.S. population.

FDA, *Adverse Event Reporting System* (Aug. 20, 2009).[11] With respect to MDRs, the FDA similarly warns that "MAUDE data is not intended to be used either to evaluate rates of adverse events or to compare adverse event occurrence rates across devices."[12]

The statistical biases in adverse event reports relate to the inconsistent, informal, and anecdotal nature of the FDA's reporting system. Although mandatory for the manufacturers of all medical devices and drugs, adverse event reporting is purely voluntary for healthcare professionals—who may be the primary source for reports, depending upon the device or drug in question. *See In re Medtronic, Inc.*, 184 F.3d 807, 809 (8th Cir. 1999). Through the FDA's "MedWatch" reporting system, physicians, physician assistants, pharmacists, and nurses may submit reports "either directly to the agency or to other entities who report to the agency" (*i.e.*, the manufacturers). *Protecting the Identities of Reporters of Adverse Events and Patients; Preemption of Disclosure Rules*, 60 Fed. Reg. 16962, 16962 (Apr. 3, 1995); *see* 21 C.F.R. §§ 803.12(d), 803.20(a). Moreover, adverse event reports from healthcare professionals are highly informal; the great majority are made orally to manufacturers. *See* General

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[11] *Available at* http://www.fda.gov/Drugs/GuidanceCompliance RegulatoryInformation/Surveillance/AdverseDrugEffects/default.htm.

[12] MAUDE, which stands for "Manufacturer and User Facility Device Experience," is the FDA's online MDR database. *Available at* http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm.

Accounting Office, *Medical Devices: Early Warning of Problems Is Hampered by Severe Underreporting ("Medical Devices")* 47 (Dec. 1986) (83% are oral reports).

Because the FDA requires manufacturers to submit duplicative adverse event reports for incidents voluntarily reported to them by healthcare providers, MedWatch "generate[s] a deluge of information." Catherine Struve, *The FDA & the Tort System: Postmarketing Surveillance, Compensation, & the Role of Litigation*, 5 Yale J. Health Pol'y, L. & Ethics 587, 604 (2005). For example, the FDA reported receiving 224,197 MDRs during its 2006 fiscal year. FDA, Center for Devices & Radiological Health, *CDRH FY 2006 Annual Report* 29 (2006).[13] A more recent report concluded that this total was even larger:

> This number increased steadily until 2006, when it increased more than fourfold to 443,066 events, and then stayed relatively flat with 449,978 events in 2007.

HHS Office of Inspector General, *Adverse Event Reporting*, at 10. That sharp increase was due to one particular manufacturer's device, *id.*, demonstrating again the volatility of the reporting system.

At the same time, while MDR totals "may seem high, underreporting of adverse events" is a persistent problem. Edward M. Basile & Beverly H. Lorell, *The Food & Drug Administration's Regulation of Risk Disclosure for Implantable Cardioverter Defibrillators: Has Technology Outpaced the Agency's Regula-*

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[13] *Available at* http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDRH/CDRHReports/ucm129258.pdf.

tory Framework?, 61 Food & Drug L.J. 251, 258 (2006). In 1986 (under earlier regulations), the General Accounting Office ("GAO") estimated that health care providers voluntarily reported only one percent of reportable events to the FDA and only about half to the manufacturers.[14] A decade later, GAO found that systemic underreporting persisted.[15] "Reasons" for underreporting:

> include ignorance of the reporting system, complacency, fear of medicolegal liability, personal or professional guilt about having inadvertently harmed a patient, and uncertainty as to whether the drug or device was actually the cause of the adverse event.

Jeffrey Zigler, et al., *Medical Device Reporting: Issues With Class III Medical Devices*, 62 Food & Drug L.J. 573, 577 (2007).

Chronic underreporting by healthcare providers allows extraneous factors to influence reporting rates. In 2005, the FDA concluded that adverse event reporting is "subject to substantial limitations in interpretation because of the inherent uncertainties in the numerator and denominator." FDA, *Guidance for Industry: Good Pharmacovigilance Practices & Pharmacoepidemiologic Assessment* ("*Good Pharmacovigilance*"), 2005 WL 3628217 § IV(G) (Mar. 2005). Thus:

> [V]oluntary adverse event reporting systems . . . are subject to a variety of reporting biases (*e.g.*,

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[14] GAO, *Medical Devices*, at 50-51.

[15] GAO, *Medical Device Reporting: Improvements Needed in FDA's System for Monitoring Problems with Approved Devices* 15-17 (Jan. 1997), *available at* http://www.gao.gov/archive/1997/he97021.pdf.

> some observations could reflect concomitant treatment, not the product itself, and other factors, including the disease being treated, other co-morbidities or unrecorded confounders, may cause the events to be reported). In addition, [the] data may be affected by the submission of incomplete or duplicate reports, underreporting, or reporting stimulated by publicity or litigation.

Id. § IV(E).

In a brief filed with the Court this Term, the Solicitor General similarly acknowledged that voluntary adverse event reporting in the vaccine context is "not sufficient" for "sound" decision making and requires "further investigation":

> Because VAERS [the vaccine adverse event reporting system] depends on self-reporting, however, its data alone are not sufficient for sound public health policy decisions. VAERS data are instead used to trigger further investigation.[16]

To cull true product risk from mere reporting biases, statistical significance—not the number of reported events—is essential. As the FDA recently explained, "[i]nformation from other sources that is neither systematically acquired nor statistically significant can provide only anecdotal information."[17]

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[16] Brief for the United States as *Amicus Curiae* Supporting Respondents, *Bruesewitz v. Wyeth, Inc*, No. 09-152, at 21-22 (U.S. July 23, 2010).

[17] FDA, Center for Devices and Radiological Health, *Guidance for Industry Assessment of Abuse Potential of Drugs* 18 (Discussion Draft Jan. 2010), *available at* http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM198650.pdf.

The FDA neither acts, nor demands that manufacturers act, upon raw adverse event reports of the sort at issue in the present case. Instead, the FDA employs statistical analysis—precisely what the Ninth Circuit rejected here.[18]

Despite the value of the FDA's adverse event reporting system, the data contained within the database is plagued by significant flaws that prevent the information from being relied upon absent such analysis:

First, no causation requirement means "that the system gets flooded with too many (generally unimportant) reports" and generates so much noise that "[k]ey data regarding new issues can get lost in this sea of irrelevant information." Ralph Hall, *A Proposed Solution to the Notification Problem*, 7 Minn. J.L. Sci. & Tech. 189, 194 (2005).

Second, "underreporting is a recognized problem . . . [p]articularly for low frequency events" where "every report is critical." *Id.*

And *third*, the FDA's "passive systems provide only a raw number of events and not the incident rate"

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[18] The FDA utilizes "trend analyses . . . such as calculating occurrence rate changes for specific events." HHS Office of Inspector General, *Adverse Event Reporting*, at 5. The FDA's latest device guidance recommends sophisticated analysis "to mine large databases of post-market medical reports" in order to "reduce the number of falsely significant associations that are expected." FDA, Center for Devices and Radiological Health, *Guidance for Industry & FDA Staff: Guidance for the Use of Bayesian Statistics in Medical Device Clinical Trials*, 2010 WL 545395 § 6 (Feb. 5, 2010). Similar forms of "data mining" are recommended for evaluating adverse drug events. FDA, *Good Pharmacovigilance*, § V.

and "may not provide a valid basis for medical decisions." *Id.*

In other words, the FDA's reporting system results in a database that is both overinclusive and underinclusive, with the biases of underreporting influenced by a variety of confounding factors. Thus, sophisticated statistical analysis is required before the information may be relied upon to draw any meaningful conclusions.

C. Numerous Courts Have Recognized that FDA Adverse Event Reports Are Insufficient for Civil Liability.

Respondents' attempt to rely upon adverse event reports to establish civil liability under the securities laws calls to mind more frequent attempts by plaintiffs in products-liability cases to mine the FDA's adverse event database for evidence of causation. In that context, too, the vast majority of federal courts have concluded that, absent statistical significance, adverse event reports are insufficient to support liability.

In seeking to fulfill its broad mandate to ensure the safety of drugs and medical devices, the FDA seeks to pull together as much information as possible in the adverse event databases, not to assemble a database of reliable reports sufficient to satisfy individual questions of causation. Such administrative analysis involves a much lower standard than necessary in a court of law:

> This methodology results from the preventive perspective that the agencies adopt in order to reduce public exposure to harmful substances. The agencies' threshold of proof is reasonably

> lower than that appropriate in tort law, which traditionally makes more particularized inquiries into cause and effect.

Allen v. Pa. Eng'g Corp., 102 F.3d 194, 198 (5th Cir. 1996) (citation and internal quotation marks omitted); *see also Rider v. Sandoz Pharm. Corp.*, 295 F.3d 1194, 1201 (11th Cir. 2002) ("A regulatory agency such as the FDA may choose to err on the side of caution."); *Glastetter v. Novartis Pharm. Corp.*, 252 F.3d 986, 991 (8th Cir. 2001) ("[M]ethodology employed by a government agency results from the preventive perspective that the agencies adopt.").

For this reason, courts in civil litigation frequently reject the scientific validity of FDA MedWatch reporting when applying scientific reliability standards under *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993). In *McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1250 (11th Cir. 2005), for instance, the court recognized that "FDA reports reflect complaints called in by product consumers without any medical controls or scientific assessment." Utilization of such reports to prove causation was unscientific, and admission of this testimony was an abuse of discretion:

> [A]necdotal reports do not prove causation . . . . Uncontrolled anecdotal information offers one of the least reliable sources to justify opinions about both general and individual causation.

Id. Mere complaints "lack[] the indicia of scientific reliability." *Id.* at 1240. *Accord Glastetter*, 252 F.3d at 989-90 (voluntary reports "make little attempt to screen out alternative causes," "frequently lack analysis," and "often omit relevant facts").

Numerous district courts ruling on *Daubert* and similar evidentiary challenges have reached the same conclusion, dismissing adverse event report data as "uncontrolled anecdotal information," *Benkwith v. Matrixx Initiatives, Inc.*, 467 F. Supp. 2d 1316, 1327 (M.D. Ala. 2006), that "suggest only a potential, untested hypothesis," *In re Breast Implant Litig.*, 11 F. Supp. 2d 1217, 1228 (D. Colo. 1998), that lack any "known or potential rate of error," *In re Baycol Prod. Litig.*, 532 F. Supp. 2d 1029, 1041 (D. Minn. 2007), and are simply "not probative of . . . notice." *Smith v. Pfizer Inc.*, 2010 WL 1754443, at *5 (M.D. Tenn. Apr. 30, 2010).[19]

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[19] *Accord In re Accutane Prod. Liab. Litig.*, 2007 WL 1288354, at *3 (M.D. Fla. May 2, 2007) (MedWatch reports "reflect[] nothing more than an assessment of a possible relationship, not an actual relationship"); *Dellinger v. Pfizer Inc.*, 2006 WL 2057654, at *9 (W.D.N.C. July 19, 2006) (reports "are not scientific proof of causation" and "cannot support a causation opinion"); *Ervin v. Johnson & Johnson, Inc.*, 2006 WL 1529582, at *6 (S.D. Ind. May 30, 2006) (reports "do little more than establish a temporal association between an exposure to a drug and a particular occurrence"), *aff'd*, 492 F.3d 901 (7th Cir. 2007); *In re Meridia Prod. Liab. Litig.*, 328 F. Supp. 2d 791, 807 (N.D. Ohio 2004) ("[P]roportional reporting rate analyses are incomplete and often misleading because they do not show the total distribution of reports."), *aff'd*, 447 F.3d 861 (6th Cir. 2006); *Dunn v. Sandoz Pharm. Corp.*, 275 F. Supp. 2d 672, 682 (M.D.N.C. 2003) (reports lack "information that would be necessary to determine . . . causation"); *Soldo v. Sandoz Pharm. Corp.*, 244 F. Supp. 2d 434, 537 (W.D. Pa. 2003) (reports "are compilations of occurrences" and "do not demonstrate a causal link but instead represent coincidence"); *Cloud v. Pfizer, Inc.*, 198 F. Supp. 2d 1118, 1133 (D. Ariz. 2001) (reports "are merely compilations of occurrences, and have been rejected as reliable scientific evidence"); *In re Diet Drugs Prod. Liab. Litig.*, 2001 WL 454586, at *15 (E.D. Pa. Feb. 1, 2001) (reports "are universally recognized as insufficient and unreliable evidence of causation"); *Hollander*

State courts applying similar scientific validity standards concur. In *Merrell Dow Pharm., Inc. v. Havner*, 953 S.W.2d 706, 720 (Tex. 1997), the court excluded "case reports" because "anecdotal . . . evidence accomplishes no more than a false appearance of direct and actual knowledge of a causal relationship." So too the Iowa Supreme Court, which recently held that FDA "[c]ase reports are merely accounts of medical events. They reflect only reported data, not scientific methodology." *Ranes v. Adams Labs., Inc.*, 778 N.W.2d 677, 693 (Iowa 2010).[20]

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v. Sandoz Pharm. Corp., 95 F. Supp.2d 1230, 1237 (W.D. Okla. 2000) (reports "are not controlled studies and do not eliminate confounding variables"), *aff'd in relevant part*, 289 F.3d 1193 (10th Cir. 2002); *Brumbaugh v. Sandoz Pharm. Corp.*, 77 F. Supp. 2d 1153, 1156 (D. Mont. 1999) (reports "don't isolate and investigate the effects of alternative causation agents," "are compilations of reported phenomena," and "reflect reported data, not scientific methodology"); *In re Norplant Contraceptive Prod. Liab. Litig.*, 1997 WL 80527, at *1 (E.D. Tex. Feb. 19, 1997) (reports excluded because "the FDA requires [defendant] to submit all adverse events reported to it without regard to whether there is any proven causal connection"); *Haggerty v. Upjohn Co.*, 950 F. Supp. 1160, 1164 (S.D. Fla. 1996) (reports "can be used to generate hypotheses" but "scientifically valid cause and effect determinations depend on controlled clinical trials and epidemiological studies"), *aff'd mem.*, 158 F.3d 588 (11th Cir. 1998); *DeLuca v. Merrell Dow Pharm., Inc.*, 791 F. Supp. 1042, 1050 (D.N.J. 1992) (reports have "inherent biases as they are second-or-third hand reports, are affected by medical or mass media attention, and are subject to other distortions"), *aff'd mem.*, 6 F.3d 778 (3d Cir. 1993).

[20] *Accord Heckstall v. Pincus*, 797 N.Y.S.2d 445, 447 (N.Y. App. Div. 2005) (MedWatch reports are "unverified listings and reporting of adverse reactions" and "are not generally accepted in the scientific community on questions of causation"); *Reynolds v. Warthan*, 896 S.W.2d 823, 828 (Tex. App. 1995) (reports only "create[] a suspicion without any medical proof").

In no other case and in no other area of the law have adverse event reports carried the weight that the Ninth Circuit gave them below.

II. THE INHERENT LIMITATIONS OF ADVERSE EVENT REPORTS PRECLUDE DRAWING ANY INFERENCE OF SCIENTER, ABSENT STATISTICAL SIGNIFICANCE.

Given the inherent limitations and biases of adverse event reports, as acknowledged by the FDA and the courts, such reports are presumptively inconclusive of a correlation—let alone a causal connection—between a product and an adverse event. They are scientifically meaningless until cumulative statistical analysis demonstrates otherwise.

In view of such limitations, there is simply no basis upon which a court could draw an inference that a company's decision not to disclose such isolated reports through a public statement to investors was suspicious in any way, much less that it supports a "strong inference" of fraudulent intent "at least as compelling as any opposing inference." *Tellabs*, 551 U.S. at 314.[21]

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[21] Adverse event reports received by medical device manufacturers are, in fact, publicly available. The FDA has authority to disclose adverse event reports to the public, *see* 21 C.F.R. § 803.9(a), and through the MAUDE online database, *see supra*, n.12, all adverse event reports involving medical devices (MDRs) are made available to the public by the FDA, subject to protection of trade secrets and patients' personal medical information. *See id.* § 803.9(b); *see also Medical Device Reporting* § 3 (explaining disclosure process).

The public availability of MDRs is a separate reason why securities fraud claims against medical device manufacturers cannot be based on the alleged non-disclosure of MDRs. *See,*

A. Non-Disclosure of Unreliable or Speculative Information to the Public Does Not Support an Inference of Scienter.

In assessing scienter in non-disclosure cases, the quality of the undisclosed information is critical. Information need not be disclosed that is inconclusive, speculative, or "of dubious significance." *Basic Inc. v. Levinson*, 485 U.S. 224, 231 (1988) (quoting *TSC Indus., Inc. v. Northway, Inc.*, 426 U.S. 438, 448

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e.g., *Santa Fe Indust., Inc. v. Green*, 430 U.S. 462, 474 (1977) (no actionable Rule 10b-5 claim where plaintiffs were "furnished with all relevant information on which to base their decision"); *see also Avon Pension Fund v. GlaxoSmithKline, PLC*, 343 Fed. App'x 671, 674 (2d Cir. 2009) (disclosure to the FDA "effectively refutes that the pleaded circumstances support the requisite inference of scienter"); *Fort Worth Empl. Ret. Fund v. Biovail Corp.*, 615 F. Supp.2d 218, 221 (S.D.N.Y. 2009) (no scienter where allegedly undisclosed letter "was publicly available on the FDA's website throughout the putative class period, where it could have been read and assessed by any investor"); *Yanek v. Staar Surgical Co.*, 388 F. Supp. 2d 1110, 1126 (C.D. Cal. 2005) (no scienter where "the MAUDE printouts were available through the FDA"; "the market already had the necessary information"). Unlike medical devices, the product at issue in the present case, Zicam, was an over-the-counter homeopathic product, and the FDA did not require mandatory adverse event reporting for such OTC medications until 2006. *See* Dietary Supplement & Nonprescription Drug Consumer Protection Act, Pub. L. 109-462, 120 Stat. 3469, *codified as* 21 U.S.C. §§ 379aa (OTC drug reporting requirements) and 379aa-1 (same for dietary supplements). The allegations in this case involved the non-disclosure of pre-2006 adverse events reports. But no matter whether a company is obliged to submit adverse event reports to the FDA, the scienter analysis should remain the same. In either case, as discussed below, scienter does not exist where a company has no reason to believe that the reports are statistically significant.

(1976)).[22] Non-disclosure of such information to the market supports no inference, much less a strong inference, of intent to deceive. In these circumstances, "the defendant did not have ***sufficient*** information at the relevant time to form an evaluation that there was a need to disclose certain information and to form an intent not to disclose it." *N.J. Carpenters*, 537 F.3d at 45 (emphasis added). Stated differently, a defendant has no "reason to believe" that non-disclosure of inconclusive or otherwise suspect information creates a danger of misleading investors. *Carter-Wallace I*, 150 F.3d at 157; *see also Schlifke v. Seafirst Corp.*, 866 F.2d 935, 946 (7th Cir. 1989) ("The question is not merely whether the [defendant] had knowledge of the undisclosed facts; rather, it is the ***danger of misleading buyers*** that must be actually known or so obvious that any reasonable man would be legally bound as knowing.") (citation and internal quotation marks omitted).

A company cannot have culpable knowledge of a product safety issue without a sound reason to believe that the product is causally linked to an adverse event. Yet until a statistically significant association is apparent, the company can draw no meaningful inferences from anecdotal reports and thus has no basis "to form an evaluation that there

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[22] *See also Teamsters Local 445 Freight Div. Pension Fund v. Dynex Capital, Inc.*, 531 F.3d 190, 196 (2d Cir. 2008) (no inference of scienter where "[plaintiffs'] broad reference to raw data lacks even an allegation that these data had been collected into reports that demonstrated" their allegations); *In re Healthcare Compare Corp. Sec. Litig.*, 75 F.3d 276, 282-83 (7th Cir. 1996) (no duty to disclose tentative internal estimates subject to revision or verification, even though they conflict with published estimates).

was a need to disclose." *N.J. Carpenters*, 537 F.3d at 45; *see also Avon*, 343 Fed. App'x at 672 ("Reports or test results must yield reliable evidence of a drug's adverse effect to give rise to a duty . . . to disclose those results to potential investors."). Absent statistical significance, the company thus has no reason to view adverse event reports as casting doubt on product safety, and without such a belief, there is no legal basis to infer an intent to deceive the public through non-disclosure.[23] Instead, the most plausible inference is that the company continued to believe that its product—marketed only after FDA review—remained safe.[24]

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[23] It should be emphasized that the statistical significance of adverse event reports is a necessary, but not a sufficient, condition to establish scienter. Scienter requires that the company also know that the reports are "sufficiently serious and frequent to affect future earnings" and threaten the "commercial viability" of the company. *Carter-Wallace I*, 150 F.3d at 157; *see also Masters v. GlaxoSmithKline*, 271 Fed. Appx. 46, 50-51 (2d Cir. 2008) (dismissing non-disclosure complaint because the statistically significant test results were "financially immaterial" as the product represented less than 3% of the company's sales). Moreover, a complaint must plead particularized allegations that support imputing knowledge of non-disclosed adverse events, as well as their significance, to each defendant. *See, e.g.*, *Winer Family Trust v. Queen*, 503 F.3d 319, 335-36 (3d Cir. 2007).

[24] *See, e.g.*, *Carter-Wallace II*, 220 F.3d at 42 ("[U]ntil a connection between [the product] and any illness could be made, we would not expect [defendant] to abandon its product on what, at the time, would have been speculation."); *State Univs. Ret. Sys. of Ill. v. AstraZeneca PLC*, 334 Fed. App'x 404, 407 (2d Cir. 2009) ("[P]laintiffs have not alleged anything to negate the idea that defendants were attempting to develop a drug that they thought [would be] beneficial and were so describing it to the public.") (quotation omitted).

The Ninth Circuit failed to appreciate the inherent inconclusiveness and unreliability of adverse event reports. Instead of viewing unverified adverse event reports with appropriate skepticism, the Ninth Circuit fell victim to their "false appearance of direct and actual knowledge of a causal relationship." *Merrell Dow*, 953 S.W.2d at 720. Nowhere in Respondents' complaint is there any allegation, much less a particularized one, that the non-disclosed adverse event reports at issue here were statistically significant. Absent that critical allegation, there is no scientific basis upon which these adverse event reports may be deemed to support causation, and thus any inference that adverse event reports were withheld with fraudulent intent is not "cogent and at least as compelling as any opposing inference of nonfraudulent intent." *Tellabs*, 551 U.S. at 314.

B. Statistically Insignificant Adverse Event Reports Can Only Support an Improper Hindsight Inference of Fraud.

This Court has observed that one recognized purpose of the "strong inference" standard for scienter is "to ward off allegations of 'fraud by hindsight.'" *Tellabs*, 551 U.S. at 319 (citations omitted). A plaintiff must allege particularized facts that the defendant's statements were false or misleading when they were made. A classic fraud-by-hindsight scenario assumes that "simply because the alleged misrepresentation conflicts with the current state of the facts, the charged statement must have been false" when made. *Grossman v. Novell, Inc.*, 120 F.3d 1112, 1124 (10th Cir. 1997) (citation and quotation marks omitted). "Corporate officials need not be clairvoyant; they are only responsible for revealing

those material facts that are reasonably available to them." *Novak v. Kasaks*, 216 F.3d 300, 309 (2d Cir. 2000). Nor are they "required to take a gloomy, fearful or defeatist view of the future; subject to what current data indicates, they can be expected to be confident." *Shields v. Citytrust Bancorp.*, 25 F.3d 1124, 1129 (2d Cir. 1994).

Securities fraud cases against life sciences companies commonly allege that "a promising drug or medical device is approved by the FDA and then later proves to have health risks which affect the market for the [product]." *N.J. Carpenters*, 537 F.3d at 47. Such suits are rife with fraud-by-hindsight claims.

> But if the management of the company releases positive reports about the drug to the public along the way which the management honestly believes to be true, and where there is no reckless disregard for truth, then that is not securities fraud, even though at a later point some event occurs which prevents the marketing of the drug or makes it necessary to take the drug off the market.

In re AstraZeneca Sec. Litig., 559 F. Supp. 2d 453, 470 (S.D.N.Y. 2008), *aff'd*, 334 Fed. App'x 404 (2d Cir. 2009).

Carter-Wallace and its progeny cogently recognize that without statistical significance, securities claims based on non-disclosure of adverse event reports to investors inherently allege "fraud by hindsight." *Carter-Wallace II*, 220 F.3d at 42.[25] The defendant is

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[25] *See also* Richard A. Nagareda, *FDA Preemption: When Tort Law Meets the Administrative State*, 1 J. Tort Law 4, 49 (2006) ("Litigation is inherently prone to play into hindsight bias. Early, speculative information—say, from anecdotal experience

blamed for not identifying product safety concerns in advance of the available data. Until scientifically valid methods reveal an association between the product at issue and adverse events, a defendant is entitled to view the reports as they are: unverified anecdotal accounts that may describe events caused by any number of things, from the condition being treated, to a simultaneously used product, to operator error, to mere chance. *See supra* at pp. 11-20. "The eventual linking of [an adverse event] to [a product] cannot relate back to the time of the [allegedly misleading] statements . . . and reflect on [a company's] reasonable belief that the reports were random." *Carter-Wallace II*, 220 F.3d at 41. The statistical significance standard directly protects against such fraud-by-hindsight abuses, such as occurred in the present case.

Indeed, the Ninth Circuit's rejection of any requirement that the non-disclosed adverse event reports be statistically significant virtually guaranteed fraud-by-hindsight. The court itself relied (Pet. App. at 2a n.1) on an FDA warning letter dated June 2009—***more than five years after*** the close of the class period. Such a *post hoc* association plainly can have no legal bearing on Petitioners' conduct during the 2003-2004 class period.

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in the absence of systematic research controls—might seem the first inkling of a drug safety problem only when framed within subsequent scientific developments").

C. It Is Prudent and Sensible for a Company To Investigate Adverse Event Reports for Statistical Significance Before Making A Public Disclosure.

Section 10(b) seeks "to achieve a high standard of business ethics in the securities industry." *SEC v. Zandford*, 535 U.S. 813, 819 (2002) (quotation omitted). "A prudent course of action . . . weakens rather than strengthens an inference of scienter." *Slayton v. Am. Express Co.*, 604 F.3d 758, 777 (2d Cir. 2010) (quoting *Horizon Asset Mgmt. v. H&R Block, Inc.*, 580 F.3d 755, 763 (8th Cir. 2009)).

Because publicly traded companies have a duty to speak accurately when they speak to their investors, "[p]rudent managers conduct inquiries rather than jump the gun with half-formed stories as soon as a problem comes to their attention." *Higginbotham v. Baxter Int'l, Inc.*, 495 F.3d 753, 760-61 (7th Cir. 2007) (Easterbrook, J.).

Far from reflecting a guilty state of mind, it is prudent and sensible for a publicly traded life sciences company to forego disclosing raw adverse event data to investors unless and until the reports are analyzed both individually and in the aggregate. Only if the reports reveal a statistically significant product safety issue could a disclosure obligation arise. *Carter-Wallace II*, 220 F.3d at 42 ("[U]ntil a connection between [a] product and any illness could be made, we would not expect [a company] to abandon its product."). Making disclosures to investors regarding unverified adverse event reports "on what, at the time, would have been speculation" about their significance, *id.*, is unquestionably irresponsible. *See TSC*, 426 U.S. at 448 (disclosure of "dubious" information "may accomplish more harm than good");

N.J. Carpenters, 537 F.3d at 58 (defendant "would have behaved irresponsibly (and possibly in violation of the securities laws) if it had made a public announcement which was possibly inaccurate because the situation of [adverse event] incidences had not yet been adequately investigated.")[26] The statistical significance standard avoids this no-win dilemma.

Perversely, the Ninth Circuit drew an inference of scienter from Petitioners' decision to investigate the handful of adverse event reports involving Zicam. The court observed that the defendants were "sufficiently concerned" about the customer complaints to "call[] [a doctor] about one of her patients who had complained" and "ask if [the doctor] would participate in studies" of the drug. (Pet. App. at 32a.) But "[k]nowing enough to launch an investigation . . . is a very great distance from convincing proof of intent to deceive." *Higginbotham*, 495 F.3d at 758. Indeed, the far more plausible inference was that Petitioners' investigative efforts reflected compliance with the FDA's guidance simply to investigate the adverse event reports—an inference that must be drawn in Petitioners' favor under *Tellabs*.

Absent statistical significance, the Ninth Circuit's conclusion that non-disclosure of adverse event reports to the public "present[ed] a danger of misleading buyers or sellers" (Pet. App. at 33a) is unwarranted as a matter of law.

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[26] *See also Higginbotham*, 495 F.3d at 761 (defendant "might more plausibly have been accused of deceiving investors had managers called a press conference before completing the steps necessary to determine just what happened"); 17 C.F.R. § 230.175(a) (forecasts made without a reasonable basis are not protected by safe harbor).

III. THE NINTH CIRCUIT'S RULE WOULD HAVE DIRE CONSEQUENCES FOR LIFE SCIENCES COMPANIES, INVESTORS, AND CONSUMERS.

Over the last decade, life sciences companies have assumed that non-disclosure of statistically insignificant adverse event reports (to anyone but the FDA) would not support an actionable securities claim under Rule 10b-5. The Ninth Circuit's contrary decision threatens a dramatic change in the status quo. Absent a statistical significance requirement, life sciences companies will be forced to make difficult decisions whether or not to disclose each and every adverse event report to the market upon receipt, with either choice creating litigation risk. Given the hundreds of thousands of adverse event reports generated annually, that burden and risk cannot be overstated.

The most obvious risk to life sciences companies from any abandonment of the statistical significance standard is present here—a securities lawsuit claiming non-disclosure of statistically insignificant adverse event reports. As all concerned with class action securities litigation are well-aware, the Rule 12(b)(6) stage carries almost "dispositive" significance, as unsuccessful defendants must decide whether to settle based on a multitude of non-merits factors, including the huge cost of protracted discovery. *See Merrill Lynch, Pierce, Fenner & Smith, Inc. v. Dabit*, 547 U.S. 71, 80 (2006) ("[L]itigation under Rule 10b-5 presents a danger of vexatiousness different in degree and in kind from that which accompanies litigation in general . . . Even weak cases brought under the Rule may have substantial settlement value . . . because '[t]he very pendency of the

lawsuit may frustrate or delay normal business activity.'") (quoting *Blue Chip Stamps v. Manor Drug Stores*, 421 U.S. 723, 739 (1975)); Tom Baker & Sean J. Griffith, *How the Merits Matters: Directors' and Officers' Insurance & Securities Settlements*, 157 U. Penn. L. Rev. 755, 820 (2009) (motions to dismiss are "dispositive" because "essentially all securities class actions that survive a motion to dismiss are [ultimately] settled with a payment to the class"). Under the Ninth Circuit's rule, every decision not to disclose an adverse event report to investors, regardless of statistical significance, could be very costly.

Overcautious companies erring on the side of mass disclosure of adverse event reports expose themselves to different, yet equally troubling, securities litigation risks. The Ninth Circuit's decision will deprive companies of the opportunity to investigate adverse event reports, or to conduct the statistical analyses recommended by the FDA, before making such disclosures. Companies opting for preemptive disclosure would do so on incomplete information. They would be in the precarious position of crafting disclosures that disclaim such events' significance, while simultaneously allowing the possibility that later analysis could reveal a different outcome.[27] Prema-

[27] The food and drug laws, rather than the securities laws, already strike the appropriate balance in disclosing raw adverse event reports. As noted above, *supra* note 21, the FDA makes adverse event reports public for certain products through FDA databases like MAUDE, where medical professionals and any other inquiring minds can seek them out. By contrast, the Ninth Circuit's decision would thrust such raw data on the market by company disclosures that may incorrectly be perceived—no matter how carefully worded—as placing the company's imprimatur on the unverified reports.

ture disclosure could also harm investors by causing an unwarranted decline in stock value (or at a minimum, an increase in volatility) until such time as a complete investigation reveals no statistically significant link.[28]

In short, companies seeking to comply with the Ninth Circuit's decision—the very companies that our society looks to research, develop and manufacture critical and life-saving medicines and medical devices—face an effectively no-win choice, were the decision below to be affirmed.

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[28] *Cf. In re MedImmune, Inc. Sec. Litig.*, 873 F. Supp. 953, 966 (D. Md. 1995) ("Where mere disclosure of [an FDA] question might cause the company's stock to decline in value, the eventual answer to the question might cause it to rise once again. Investors who sold that stock when the FDA's question was asked but before the company's answer was given might have legitimate cause for concern."); *accord In re Biogen Sec. Litig.*, 179 F.R.D. 25, 37 (D. Mass. 1997).

CONCLUSION

For the reasons explained, the judgment of the United States Court of Appeals for the Ninth Circuit should be reversed.

Respectfully submitted,

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AMICUS CURIAE BRIEF

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v.

JAMES SIRACUSANO, ET AL.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

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BRIEF OF BAYBIO AS AMICUS CURIAE SUPPORTING PETITIONERS

BayBio respectfully submits this brief as amicus curiae in support of petitioners.[1]

INTEREST OF AMICUS CURIAE

Amicus curiae BayBio is an independent, non-profit trade association serving the life science industry in Northern California. Northern California is the birthplace of the biotechnology industry and contains the largest cluster of life sciences companies in the United States. Amicus's membership consists of more than 400 organizations engaged in or supportive of research, development, and commercialization of life science products. Amicus supports the Northern California bioscience community through advocacy, enterprise support, and the enhancement of research collaboration. Amicus represents the point of view of the life science industry on issues at every level of government, regularly working with legislators, officials, and policymakers.

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[1] Pursuant to Rule 37.3(a), letters from the parties consenting to the filing of this brief have been filed with the Clerk of the Court. No counsel for a party authored this brief in whole or in part, and no party or counsel for a party made a monetary contribution intended to fund the preparation or submission of the brief. No person other than amicus curiae, its members, or its counsel made a monetary contribution to the preparation or submission of this brief.

Amicus is concerned that the decision below will expose its membership to potential liability for securities fraud for failing to disclose isolated reports of adverse events, even when those reports do not constitute medically or statistically significant evidence that the adverse events were caused by use of a drug.

SUMMARY OF ARGUMENT

The Nation's leading biotechnology companies produce and develop important as well as life-saving drugs. They are constantly inundated with adverse event reports and other data about the efficacy and safety of their products in clinical trials and on the market. These companies—many of which are members of amicus BayBio—thoroughly investigate these reports and, when required by law, transmit the reports to government regulators for further analysis.

They do not, however, routinely disclose the existence of adverse event reports when making statements about their financial results or the safety and efficacy of their products. That is so because adverse event reports, without more, say nothing about whether the drug caused the adverse event—let alone whether the drug is safe or effective. Accordingly, at least when a company is not making a statement expressly about adverse event reports, the non-disclosure of these reports cannot state a claim under Section 10(b) and Rule 10b-5.

A.

1. Biotechnology companies regularly receive reports of adverse events from users of their products or from those participating in clinical trials. While such anecdotal evidence may prompt further inquiry into a drug's safety, it does not, standing alone, constitute scientific evidence that the drug causes a dangerous or undesirable reaction. Indeed, history has demonstrated that anecdotal evidence of correlation

is often misleading, and reliance on it can result in erroneous conclusions. Such speculative, uninformed conclusions are particularly pernicious when they cause consumers to stop using safe, beneficial pharmaceutical drugs or when they discourage people from participating in clinical trials.

In contrast with anecdotal evidence, more reliable data can be derived from controlled experiments (i.e., clinical trials) and observational studies. In such studies, only a statistically significant deviation between the incidence of a result in the treatment group as compared to the control group is evidence of correlation, and possibly causation, between the two. Scientists rely not on anecdotal evidence but on these scientific investigations to determine whether detrimental side effects are associated with a drug or are the result of chance or some other factor.

2. Pre-market approval for drugs is a rigorous process. The Food and Drug Administration (FDA) carefully considers sophisticated studies conducted by the drug manufacturer; it does not rely on anecdotal evidence of efficacy or safety. And once a drug has been approved, the FDA continues actively to monitor drug safety by collecting adverse event reports. Indeed, drug manufacturers are required by statute to report adverse events to the FDA. Recognizing that these reports are not necessarily an indication of a safety concern associated with use of a particular drug, the FDA investigates whether the adverse reports signal the possibility of a safety problem or are just statistical "noise." Many times, the FDA

determines that such reports are associated not with the drug's use but with other factors, such as underlying disease. The measured, scientific approach taken by the FDA is in sharp contrast with that of the Ninth Circuit's decision, which would lead to public disclosure of anecdotal reports of adverse events that are not statistically significant.

3. Improper or premature disclosure of adverse event reports to the public may create false alarms that discourage participation in clinical trials or cause individuals to reduce their use of beneficial medications, thereby creating a different hazard. Only if a statistically significant connection between use of the drug and the adverse event is established is there any meaning from the incidence of the adverse event.

B.

1. Unless adverse event reports are statistically significant, a plaintiff bringing a securities fraud suit cannot establish that their non-disclosure rendered the defendant's general statements about its products and business materially misleading. For an omitted fact to be material, there must be a substantial likelihood that a reasonable investor would have viewed the fact as significantly altering the total mix of information available. But, just as the FDA and biotechnology companies do not view anecdotal reports of adverse events as establishing causation, or even correlation, there is no substantial likelihood that a reasonable investor would view such reports as

having any bearing on the safety of a drug, unless those events occur to a statistically significant degree.

2. There also can be no "strong inference" of scienter, which is the pleading standard for securities fraud actions. A defendant acts with scienter when he or she makes a statement knowing that it is materially misleading. Biotechnology executives who make statements about a company's products or business, but do not address adverse events (one way or the other), are not trying to mislead investors. To the contrary, they avoid making statements about adverse events because doing so would not inform investors of meaningful information and threatens to mislead or confuse. Moreover, in determining whether allegations create a strong, (i.e., cogent or compelling) inference of scienter, courts must examine opposing, nonculpable explanations for the defendant's conduct. Because no plausible inference can be drawn from statistically insignificant adverse event reports, an allegation that the defendant was aware of, but did not disclose, such reports cannot create a strong inference of intentional deceit.

ARGUMENT

THE NON-DISCLOSURE OF STATISTICALLY INSIGNIFICANT ADVERSE EVENT REPORTS DOES NOT MAKE A COMPANY'S STATEMENTS ABOUT ITS PRODUCTS OR EARNINGS FRAUDULENT UNDER THE SECURITIES LAWS

Biotechnology companies constantly make statements to investors about their company, their existing products, and new products that are being developed or are in clinical trials. These statements are made not only in filings with the Securities and Exchange Commission, but also in press releases, conference calls, and other similar situations. The Ninth Circuit's ruling will subject companies to potential liability for securities fraud, and attendant litigation costs, any time that they make such routine statements without disclosing reports of adverse events. That decision is erroneous.

As this Court has explained, "[s]ilence, absent a duty to disclose, is not misleading under Rule 10b-5." *Basic Inc. v. Levinson*, 485 U.S. 224, 239 n.17 (1988). Such a duty to disclose may arise where the omitted fact is "necessary in order to make statements made, in the light of the circumstances under which they were made, not misleading." 17 C.F.R. § 240.10b-5(b). Thus, in determining whether any particular omission is fraudulent, the statements being made must be carefully examined.

As discussed below, statements about a company's product, its earnings, or even about effects caused by its product are not made materially misleading by the non-disclosure of adverse event reports, unless the adverse event reports are statistically significant. Nor can a company have acted with scienter in not disclosing such unreliable, statistically insignificant data. That is so because adverse events that do not occur at a statistically significant rate do not alone say anything—positive or negative—about whether a drug causes any particular side effect.

If left standing, the Ninth Circuit's rule will require companies to make boilerplate disclosures of adverse event reports virtually every time that they make a statement, along with a disclaimer that the company does not believe that such reports have any bearing on their statements. Such an information dump will add nothing to the mix of information already available to reasonable investors. At the same time, such disclosures will needlessly cause consumers to avoid using safe, beneficial drugs.

A. Biotechnology Companies Are Constantly Inundated With Anecdotal Evidence That Does Not Indicate Any Safety Risk

There is good reason for not disclosing anecdotal adverse event reports every time a company makes a statement about its products. Often these events,

upon further investigation, are found not to be caused by use of the drug. As explained below, unless the occurrence of adverse events is, at a minimum, statistically significant, there is no basis to say that use of the product led to the adverse event. This principle is universally recognized in the scientific community, by the Food and Drug Administration, and by drug developers and manufacturers. And before the decision below, it had widespread acceptance in the courts.

1. Anecdotal evidence about the efficacy or dangerousness of a product does not establish causation

Anecdotal evidence—such as the adverse events at issue in this case—is frequently subject to misinterpretation. Such evidence is often "obtained haphazardly or selectively, and the logic of 'post hoc, ergo propter hoc' does not suffice to demonstrate that the first event causes the second." David H. Kaye & David A. Freedman, *Reference Guide on Statistics*, *in* REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 83, 91 (Federal Judicial Center, 2d ed. 2000). While anecdotal evidence can be informative, it is "more useful as a stimulus for further inquiry than as a basis for establishing association." *Ibid.*

Indeed, history has demonstrated that overreliance on anecdotal evidence can lead to erroneous conclusions that mask the actual underlying cause of

a problem. Anecdotal evidence that people living by roads developed lung cancer once led to the misconception that lung cancer was caused by the fumes from the tarring of roads. *Tarred Roads & Lung Cancer*, 1 BRIT. MED. J. 178 (1940). But while people exposed to tar fumes did develop lung cancer, so too did people at a similar rate who were never exposed to such fumes. The anecdotal evidence hid the fact that the real difference between the person who developed lung cancer and the person who did not was exposure to cigarette smoke. Richard Doll & A.

Bradford Hill, *A Study of the Aetiology of Carcinoma of the Lung*, 2 BRIT. MED. J. 1271 (1952).[2]

In contrast to anecdotal evidence, more reliable data are derived from controlled experiments and, at times, observational studies. In determining the efficacy or potential dangerousness of a drug, amicus's members often view controlled experiments as

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[2] Courts have long recognized that anecdotal evidence does not establish causation. *See Hendrix v. Evenflo Co.*, 609 F.3d 1183, 1197 (11th Cir. 2010) ("Case studies and clinical experience, used alone and not merely to bolster other evidence, are also insufficient to show general causation."); *Hollander v. Sandoz Pharms. Corp.*, 289 F.3d 1193, 1211 (10th Cir.) (case reports "contain only limited information" and are "unreliable evidence of causation"), cert. denied, 537 U.S. 1088 (2002); *Turner v. Iowa Fire Equip. Co.*, 229 F.3d 1202, 1209 n.5 (8th Cir. 2000) ("Case reports are generally not considered reliable evidence of causation."); *Allison v. McGhan Med. Corp.*, 184 F.3d 1300, 1316 (11th Cir. 1999) ("case reports and case studies are universally regarded as an insufficient scientific basis for a conclusion regarding causation because case reports lack controls" (quoting *Hall v. Baxter Healthcare Corp.*, 947 F. Supp. 1387, 1411 (D. Or. 1996)); *Muzzey v. Kerr-McGee Chem. Corp.*, 921 F. Supp. 511, 519 (N.D. Ill. 1996) ("Anecdotal reports * * * are not reliable bases to form a scientific opinion about a causal link."); *Casey v. Ohio Med. Prods.*, 877 F. Supp. 1380, 1385 (N.D. Cal. 1995) ("case reports are not reliable scientific evidence of causation, because they simply describe reported phenomena without comparison to the rate at which the phenomena occur in the general population or in a defined control group"); *Merrell Dow Pharms., Inc. v. Havner*, 953 S.W.2d 706, 720-721 (Tex. 1997) ("[A]necdotal * * * evidence accomplishes no more than a false appearance of direct and actual knowledge of a causal relationship." (citing David Rosenberg, *The Causal Connection in Mass Exposure Cases: A "Public Law" Vision of the Tort System*, 97 HARV. L. REV. 851, 870 (1984))), cert. denied, 523 U.S. 1119 (1998).

the "gold standard" for evidenced-based medicine. Donald W. Miller, Jr. & Clifford G. Miller, *On Evidence, Medical & Legal*, 10 J. AM. PHYSICIANS & SURGEONS 70, 71 (2005); *see also* Jerry Avorn, *In Defense of Pharmacoepidemiology*, 357 NEW ENG. J. MED. 2219, 2219 (2007).

A controlled experiment "compare[s] outcomes for subjects who are exposed to some factor—the treatment group—and other subjects who are not so exposed—the control group." Kaye & Freedman, *supra*, at 92; *see also* Paul R. Rosenbaum, *Observational Study*, *in* 3 ENCYCLOPEDIA OF STATISTICS IN BEHAVIORAL SCIENCE 1451, 1451 (2005) ("In the ideal, the effects caused by treatments are investigated in experiments that randomly assign subjects to treatment or control, thereby ensuring that comparable groups are compared under competing treatments."). By using a treatment and a control group, particularly when the two groups are randomized, the results can demonstrate a high degree of confidence in the existence or absence of causation. In other words, when there is a certain minimum deviation between the results among the treatment group versus the control group, there is statistically significant evidence of causation. Thus, while doctors think that taking aspirin reduces the risk of heart attack based on their observations, a controlled experiment to support that hypothesis must not only compare the heart attack rates for the treatment group (those who took aspirin) and the control group (those who did not), but it also must account for potential biases

between the two groups. If the control group is healthier than the treatment group, the result of the study will be biased against the drug. Kaye & Freedman, *supra*, at 93.

To be sure, not every experiment or study can control for variables.[3] Thus, amicus's members often must rely on statistical analyses that are derived from observational studies rather than controlled experiments. Like a controlled experiment, observational studies compare two groups—a treatment group and a control group—but who is in the control versus the treatment group is not dictated by the investigator.

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[3] Particularly in the field of medicine, ethical standards sometimes preclude the use of controlled experiments:

> Experiments with human subjects are often ethical and feasible when (a) all of the competing treatments under study are either harmless or intended and expected to benefit the recipients, (b) the best treatment is not known, and in light of this, subjects consent to be randomized, and (c) the investigator can control the assignment and delivery of treatments. Experiments cannot ethically be used to study treatments that are harmful or unwanted, and experiments are not practical when subjects refuse to cede control of treatment assignment to the experimenter. When experiments are not ethical or not feasible, the effects of treatments are examined in an observational study.

Rosenbaum, *supra*, at 1451; *see also* Nick Black, *Why We Need Observational Studies to Evaluate the Effectiveness of Health Care*, 312 BRIT. MED. J. 1215 (1996).

An observational study into the efficacy of aspirin preventing heart attacks, for instance, will also observe whether there is a decreased rate of heart attacks for those who take aspirin (treatment) versus those who do not (control). If the treatment group rate is a certain degree higher or lower than the control group, it is statistically significant, and there generally is an *association* between aspirin and heart attacks. But that does not necessarily show *causation*—i.e., that aspirin reduces or increases the likelihood of a heart attack—because the observational study's methodology might not account for the possibility that some other factor in one group versus the other led to the result. Rosenbaum, *supra*, at 1451 ("When subjects are not assigned to treatment or control at random, when subjects select their own treatment or their environments inflict treatments upon them, differing outcomes may reflect these initial differences rather than effects of the treatments.").[4]

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[4] Observational studies can remove or account for biases in group selection. Rosenbaum, *supra* at 1451. For example, biases might be removed if an association "is seen in studies of different types among different groups. This reduces the chance that the observed association is due to a defect in one type of study or a peculiarity in one group of subjects." Kaye & Freedman, *supra*, at 95; *see also* Rosenbaum, *supra*, at 1455-1456.

2. *Regulators and biotechnology companies carefully scrutinize adverse event reports*

Review of adverse event reports by biotechnology companies and government regulators is one part of a drug's "rigorous" preapproval process. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 317 (2008). Adverse events that occur during a drug's preapproval clinical trials are reported to the FDA and investigated. And after a product has received approval from the FDA and has been released to the market, observations about the drug's safety continue. Amicus's members regularly receive or uncover anecdotal reports of adverse events that may or may not be associated with a drug's safety.[5]

But, as discussed above, an adverse event report is anecdotal evidence, and thus does not, by itself, establish a safety concern. For one thing, a report of an adverse event that is received by a biotechnology company does not even necessarily mean that an adverse event has, in fact, occurred. Pet. Br. 20 (citing S. Rep. No. 109-324, at 6 (2006)); *Saari v.*

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[5] In this case, respondents allege that petitioners failed to disclose adverse event reports that were received after a drug went on the market, but such anecdotal reports also arise in clinical trials and testing during the preapproval phase. Under the ruling below, non-disclosure of preapproval adverse event reports may also prompt allegations of securities fraud, because stock prices of biotechnology companies are influenced not only by the success of products already on the market but also by the potential viability of products being tested before approval.

Merck & Co., 961 F. Supp. 387, 394 (N.D.N.Y. 1997) (adverse event report is "simply a report of what plaintiff told [her doctor] about what she believed was her reaction to the [drug]"). And absent investigation, there is often no way to discern which reports signal a safety concern and which are merely background "noise."

That is especially so where the adverse event is the type that has a high incidence among the general population, such as heart disease. Institute of Med. of the Nat'l Academies, *The Future of Drug Safety: Promoting and Protecting the Health of the Public* 54 (Alina Baciu et al. eds. 2007) ("IOM Report").[6] For example, if a patient has a heart attack and dies, the manufacturers of drugs being taken by the patient to treat the heart disease at the time of the heart attack may be notified that an adverse event has occurred while someone was taking one of their drugs. Since heart attack and death may occur due to heart disease, it is difficult to determine whether drugs taken to treat heart disease played a role in the death or whether the underlying disease or diseases caused the death. If the patient was taking multiple drugs at the time of the event and/or has other diseases that may have a negative impact on the heart, it is

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[6] The IOM Report was commissioned by the FDA to study and make recommendations regarding the effectiveness of its postmarketing safety evaluations. The report was the basis of Congressional expansion of the FDA's postmarketing authority in the Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823.

even more difficult to determine whether a particular drug or combination of drugs caused the adverse event. Furthermore, events such as heart attacks are often multifactorial and not necessarily attributable solely to one factor. Drug companies and the FDA are thus left to analyze a large number of reports collected over a period of time and to look for patterns (or safety signals) in a number of these reports that would suggest a particular drug or combination of drugs may cause or contribute to particular adverse events. Often, therefore, controlled experiments or sophisticated observational studies are needed to assess whether common adverse events (such as heart attacks in older adults) can be attributed to a drug's use. *Id.* at 106. And because adverse events occur with more frequency among segments of the population that already are more susceptible to complications or disease than the general population, determining whether an adverse event is caused by the drug or by another factor—or even is occurring at random—is rarely straightforward.

Rigorous assessment of adverse events is therefore critical to evaluate a drug's safety. The FDA recognizes that adverse events will occur in clinical trials during the preapproval process and imposes certain reporting requirements. *See, e.g.*, 21 C.F.R. § 312.32(c)(1)(i). But the FDA does not require that all adverse events be reported to the institutional review board that has been designated to review the study or trial. Rather, the FDA recognizes that some adverse events are statistically insignificant, while others require further investigation or immediate action.

To that end, an adverse event "observed during the conduct of a study should be considered an unanticipated problem involving risk to human subjects, and reported to the [institutional review board], ***only*** if it were unexpected, serious, and would have implications for the conduct of the study." FDA, U.S. Dep't of Health & Human Servs., *Guidance for Clinical Investigators, Sponsors, and IRBs: Adverse Event Reporting to IRBs—Improving Human Subject Protection* at 3 (Jan. 2009), http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm079753.pdf. An individual occurrence of an adverse event ordinarily does not satisfy these criteria. *Ibid.* Nor do adverse events that "are commonly associated with the underlying disease process that the study intervention is intended to treat (e.g., deaths in a cancer trial) or that are otherwise common in the study population independent of drug exposure (e.g., cardiovascular events in an elderly population)." *Ibid.*

Nor does inquiry into the safety of a drug end after FDA approval. Due to the limited sample size and duration of use by trial participants during the preapproval process, clinical trials do not always identify every adverse event. Margaret Gilhooley, *Addressing Potential Drug Risks: The Limits of Testing, Risk Signals, Preemption, and the Drug Reform Legislation*, 59 S.C. L. REV. 347, 360-361 (2008). Adverse events that are rare may go undetected, or their incidence may be at a rate so low that it is not possible to distinguish between an event

caused by the drug and one expected by chance. IOM Report, *supra*, at 106. Thus, although safety concerns are uncovered during the preapproval stage, adverse events are not unexpected. And Congress expects that biotechnology companies will continue to monitor and study their drugs to determine whether there are adverse side effects resulting from their use, or known events with an increased incidence.

Congress thus has charged the FDA not only with making the initial drug-approval determination—which is based on whether the drug's benefits outweigh its risks—but also with monitoring drug safety after approval. *See* 21 U.S.C. § 355(k)(3), (4). The FDA requires drug manufacturers to report to the FDA serious, unexpected adverse events within 15 days of their initial receipt. 21 C.F.R. § 314.80(c)(1).[7] For all other adverse events, the manufacturer must submit to the FDA reports summarizing such events quarterly for the first three years and annually thereafter. *Id.* § 314.80(c)(2); *see also* 21 U.S.C. § 355(k)(1) (requiring manufacturers to make such reports to the FDA in accordance with FDA regulations). The FDA also has a voluntary reporting system, MedWatch, which enables healthcare providers and consumers to

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[7] A serious adverse event is one that results in, or that requires medical or surgical intervention to prevent, death or the immediate risk of death, inpatient hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect. 21 C.F.R. § 314.80(a). An unexpected adverse event is one that is not listed in the current labeling for the product. *Ibid.*

report adverse events directly to the FDA. *See* FDA, *MedWatch: The FDA Safety Information and Adverse Event Reporting Program*, http://www.fda.gov/Safety/MedWatch/default.htm (last updated Aug. 25, 2010). Last year, the FDA received more than 580,000 adverse event reports. FDA, *Reports Received and Entered into AERS by Year* (Mar. 31, 2010), http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm070434.htm.

The FDA recognizes that the receipt of adverse event reports is not necessarily an indication of a safety concern associated with use of a drug. FDA, *Annual Adverse Drug Experience Report: 1996* at 2 (1997), http://druganddevicelaw.net/Annual%20Adverse%20Drug%20Experience%20Report%201996.pdf ("For any given [adverse event report], there is no certainty that the suspected drug caused the [event]. * * * The adverse event may have been related to an underlying disease for which the drug was given, to other concomitant drugs, or may have occurred by chance at the same time the suspect drug was administered."). Otherwise, of course, the FDA would take action on receipt of *any* such report, which it does not do. That it takes no action is not surprising because, without any control group against which to measure the adverse event report, these reports demonstrate nothing about causation. *Cf.* Kaye & Freedman, *supra*, at 95 ("Was there a control group? If not, the study has little to say about causation."). Rather, once the FDA receives sufficient numbers of adverse reports, it decides whether the reports are a real

signal indicating the possibility of a safety problem, or "just 'noise' in the system." IOM Report, *supra*, at 110.[8]

And even when adverse event reports are identified as a safety "signal," such "[s]ignals generally indicate the need for further investigation, which may or may not lead to the conclusion that the product caused the event" or that "it represents a potential safety risk." FDA, *Guidance for Industry: Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment* at 4 (Mar. 2005) ("FDA Guidance for Industry"), http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126834.pdf. To that end, the FDA can require drug manufacturers to conduct postmarketing studies or clinical trials to assess drug safety when, "on the basis of scientific data deemed appropriate by the [FDA]," there are signals or the potential of serious risk related to use of the drug. 21 U.S.C. § 355(o)(3)(a).

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[8] Indeed, as data collection has become more sophisticated, the number of adverse event reports has become overwhelming, and new systems are needed to analyze the reports. But such systems can "generate errant signals that turn out to be false alarms." Jerry Avorn & Sebastian Schneeweiss, *Managing Drug-Risk Information—What to Do with All Those New Numbers*, 361 NEW ENG. J. MED. 647, 648 (2009). In particular, with the use of "automated algorithms" to "search for associations between medication use and adverse events in large observational data sets, rigorous analytic techniques will be necessary to ensure that confounding does not produce spurious associations that could generate safety signals warning of nonexistent hazards." *Ibid.*

3. The public is not served when anecdotal information, rather than statistically significant information, is disclosed

The scientific community, biotechnology companies, and the FDA all recognize that reliance on anecdotal evidence is not a sound way to demonstrate that a drug is effective or unsafe. But that does not mean such information is ignored. As discussed above, amicus's members rigorously examine the degree to which adverse event reports require further scientific study or other action, and they dutifully report, as required by law, adverse events to the FDA. The FDA, in turn, studies the reports, and takes any action when necessary—either through ordering studies, modifications to labeling or, in some instances, a withdrawal of the drug from the market.

This deliberative examination recognizes that the FDA is charged with determining, during the drug approval process, that the drug's societal benefits sufficiently outweigh its safety concerns. And it provides biotechnology companies and regulators adequate time to vet scientific data to ensure that individuals do not prematurely quit (or decline to participate in) clinical trials, or that patients do not prematurely discontinue use of beneficial drugs, due to public misperceptions of dangerousness. It also helps ensure that such drugs are not prematurely pulled from the market. Indeed, even when the FDA investigates an adverse event report, it often finds

insufficient evidence to link the drug to the adverse event or concludes that the events were caused, not by the drug, but the underlying disease, patient's age, or other treatment. *See* FDA Guidance for Industry, *supra*, at 9; FDA, *Postmarketing Drug Safety Evaluations*, http://www.fda.gov/Drugs/GuidanceCompliance RegulatoryInformation/Surveillance/ucm204091.htm (last updated June 22, 2010) (FDA investigation determined that adverse events reported for Bystolic, Doribax, and Pristiq were not caused by use of the drugs).

But the ruling below has the potential to undermine that goal. Under the Ninth Circuit's standard, even where a biotechnology company discloses scientifically established risks associated with its drugs, its statements about its financial results or products may still be materially misleading if the company does not also disclose all anecdotal reports of adverse events—notwithstanding the lack of any indication of a linkage between the adverse event and the drug. Such forced disclosure of unreliable data harms the public by potentially discouraging consumers from using therapeutic drugs. And it discourages people—who already are informed in detail about the risks associated with clinical trials—from participating in such trials due to anecdotal reports that may have no bearing on the safety of the drug being studied.[9] Both

[9] Amicus's members already have difficulty finding volunteers for clinical trials. Without these trials, the approval process for potentially life-saving drugs can be delayed.

these results, in turn, will harm investors of the companies that manufacture the drug.

These concerns are anything but inchoate. When doctors and consumers learn of reports of adverse events (particularly from the company itself), they understandably become reluctant to prescribe and use those drugs, even when there is no evidence from scientific studies to support any association between the drug and the adverse event. Judyth Pendell, AEI-Brookings Joint Center for Regulatory Studies, *The Adverse Side Effects of Pharmaceutical Litigation* at 7 (Sept. 2003) (in a poll of health care professionals and patients, "[a] sizable number of physicians (43%) have avoided prescribing a particular drug that was appropriate for a patient because they were aware that it might be involved in product liability litigation"). And companies, rather than face potentially staggering liability under United States securities laws, now have an incentive to prematurely disclose such reports, even if it is not scientifically responsible to do so.

For example, rather than wait for a study to be carefully vetted, pharmaceutical companies Merck & Co. and Schering-Plough Corp. announced that preliminary results of a clinical study showed an increased risk of cancer in patients taking Vytorin. Shirley S. Wang & Ron Winslow, *More Vytorin Bad News Hits Merck, Schering*, WALL ST. J., July 22, 2008, at B1. This announcement caused significant same-day declines in the prices of the two companies' shares. *Ibid.* A few months later, however, the

researchers published the study's full results, and the FDA concluded it was "unlikely" that Vytorin increases the risk of cancer. Jared A. Fovole, *FDA: Vytorin, Zetia 'Unlikely' To Raise Cancer Risk*, Dow Jones Newswires, Dec. 22, 2008. Vytorin remains on the market today.

In making the early disclosure, the companies wanted to inform regulators and investors immediately. But the companies' decision to disclose the results of the study before it had been carefully vetted by outside experts was widely criticized. Sarah Rubenstein, *Were Vytorin Cancer Data Made Public Too Soon?*, WALL ST. J. HEALTH BLOG (Sept. 3, 2008, 9:02 AM), http://blogs.wsj.com/health/2008/09/03/were-vytorin-cancer-data-made-public-too-soon/ (noting that a Merck spokesman explained that the criticism "makes us feel like we're damned if we do and we're damned if we don't"); Matthew Herper, *Vytorin Study's Ethical Morass*, FORBES, Sept. 3, 2008, http://www.forbes.com/2008/09/02/vytorin-cholesterol-schering-biz-healthcare-cx_mh_0903vytorin.html. There was a significant concern that patients or doctors would make health decisions based on inconclusive or erroneous information. *Ibid.* As a pathology professor explained: "Now you've got a fear out there that I don't think is justified that I think patients and physicians will be reticent to use a drug that I think is very useful clinically." *Ibid.*; *see also* Michael Shermer, *How Anecdotal Evidence Can Undermine Scientific Results*, SCIENTIFIC AMERICAN, Aug. 2008, http://www.scientificamerican.com/article.cfm

?id=how-anecdotal-evidence-can-undermine-scientific-results (noting that, despite the absence of any scientific causal link between vaccines and autism in children, anecdotal evidence often appears so "powerful that they cause people to ignore contrary evidence").

B. Where The Company's Statement Is Not Expressly About Adverse Events, A Securities Fraud Plaintiff Cannot Demonstrate A Materially Misleading Statement Or Scienter From The Non-Disclosure Of Adverse Event Reports That Are Not Statistically Significant

In addition to undermining the deliberative process by which adverse events are examined, the decision below cannot be reconciled with this Court's holdings regarding materiality and scienter. As noted, the Ninth Circuit held that drug manufacturers' statements about their products may be materially and intentionally misleading, and therefore fraudulent under the federal securities laws, unless manufacturers also disclose the occurrence of adverse events, even when those events lack any statistically significant relationship to the use of the drug. But unless the incidence of adverse events among users of a drug is at a rate that is, to a statistically significant degree, higher than among non-users, there is no evidence that the drug is the cause of the adverse events. Thus, reports of adverse events occurring at a statistically insignificant rate need not be disclosed because their non-disclosure does not make the company's statements materially misleading. And a

manufacturer cannot have acted with scienter in not disclosing information that is not evidence of a causal relationship between the drug and the adverse events.

1. The non-disclosure of statistically insignificant data does not render a company's statements materially misleading

a. To prevail on a securities fraud claim under Section 10(b) and Rule 10b-5, the plaintiff must prove that the defendant made a statement that was misleading as to a material fact. *Basic*, 485 U.S. at 238; 17 C.F.R. § 240.10b-5. "It is not enough that a statement is false or incomplete, if the misrepresented fact is otherwise insignificant." *Basic*, 485 U.S. at 238.

"Silence, absent a duty to disclose, is not misleading * * * ". *Id.* at 239 n.17. For an omission to be materially misleading, "there must be a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available." *Id.* at 231-232 (quoting *TSC Indus., Inc. v. Northway, Inc.*, 426 U.S. 438, 449 (1976)). "[A]n omitted fact is material if there is a substantial likelihood that a reasonable shareholder would consider it important" in making an investment decision. *Id.* at 231 (quoting *TSC Indus.*, 426 U.S. at 449).

Biotechnology companies, including amicus's members, routinely make statements about their products in various contexts. At least when the statements are not expressly about adverse event reports, the non-disclosure of anecdotal reports of adverse events occurring among users of a drug does not render those statements materially misleading. There is no evidence of a causal relationship between use of the drug and the incidence of the adverse events. As discussed above, anecdotal reports of isolated adverse events are inherently unreliable. Without more, they are not scientifically conclusive evidence, because "[s]ome adverse events may be expected to occur randomly, especially with a drug designed to treat people that are already ill." *In re Carter-Wallace, Inc. Sec. Litig.*, 220 F.3d 36, 41 (2d Cir. 2000). The hypothetical reasonable investor already knows that adverse event reports are to be expected, both during a drug's preapproval clinical trials and after it is placed on the market, and that such anecdotal evidence, without more, does not signify a safety issue. A reasonable investor would rely on scientifically grounded evidence about a drug's safety in making investment decisions, not on speculative, conjectural information such as isolated adverse event reports. *See In re Rockefeller Center Props., Inc. Sec. Litig.*, 184 F.3d 280, 290 (3d Cir. 1999) ("In determining the effect of an omission, we examine whether the information omitted is speculative or unreliable * * * or if it is contingent." (internal citation omitted)).

Accordingly, when making statements about a biotechnology company's products, there is no duty to also disclose statistically insignificant instances of adverse events. There is no substantial likelihood that a reasonable investor would view reports of such adverse events—which do not scientifically establish any concern about the safety of a drug—as having any bearing on the drug's commercial viability or on the drug company's earnings. Thus, "[d]rug companies need not disclose isolated reports of illnesses suffered by users of their drugs until those reports provide statistically significant evidence that the ill effects may be caused by—rather than randomly associated with—use of the drugs and are sufficiently serious and frequent to affect future earnings." *In re Carter-Wallace, Inc. Sec. Litig.*, 150 F.3d 153, 157 (2d Cir. 1998); *see also Oran v. Stafford*, 226 F.3d 275, 284 (3d Cir. 2000) (Alito, J.) ("Had [defendant] simultaneously disclosed * * * the adverse reaction reports [that lacked statistical significance], the aggregate of available information would nevertheless have led a reasonable investor to the same conclusion—that the relationship between the two drugs and heart valve disorders was still inconclusive.").

This is true even though disclosure of statistically insignificant adverse reports could prompt individual users of the drug to prematurely discontinue its use. *See* pp. 24-26, *supra*. Anecdotal reports of adverse events, although not a scientific basis for concern, could prompt especially risk-averse

consumers to avoid use or find alternative treatments. But that reaction among users is of no moment to the question whether non-disclosure of information renders prior statements materially misleading. The securities laws require disclosure based on whether a hypothetical, objectively reasonable investor would consider the information significant. *TSC Indus.*, 426 U.S. at 445. Companies have never been subject to a judgment for fraud based on the non-disclosure of objectively meaningless information, even if there are some persons who might (irrationally) act based on that information. For example, except in limited circumstances, companies are not required to comment on speculative information, *see, e.g.*, *Nathenson v. Zonagen Inc.*, 267 F.3d 400, 422 (5th Cir. 2001); *General Elec. Co. v. Cathcart*, 980 F.2d 927, 935-936 (3d Cir. 1992), or to republish rumors, *see, e.g.*, *SEC v. Monarch Fund*, 608 F.2d 938, 942-943 (2d Cir. 1979). Thus, a plaintiff cannot allege and pursue a claim for fraud when a company fails to disclose meaningless, transitory information about products, such as the delay of shipments due to a tropical storm, even if rumors of the delays might cause a temporary decline in the stock's price. And for good reason: the disclosures are supposed to inform the market, not to mislead it. Yet the Ninth Circuit's rule would subject companies to after-the-fact liability for fraud due to non-disclosure of information that is, by definition, random.

b. Moreover, in addition to discouraging doctors and patients from prescribing and using the drugs,

see pp. 24-26, *supra*, the decision below will require disclosure of reports that may inject confusion into the marketplace. "The role of the materiality requirement is * * * to filter out essentially useless information that a reasonable investor would not consider significant * * * ." *Basic*, 485 U.S. at 234. The securities laws do not require excessive disclosure, which would deluge the market with needless, irrelevant, possibly misleading data that might drown out important information that would otherwise enhance investment decisionmaking. *See id.* at 231 ("a minimal [materiality] standard might bring an overabundance of information within its reach, and lead management 'simply to bury the shareholders in an avalanche of trivial information—a result that is hardly conducive to informed decisionmaking'" (quoting *TSC Indus.*, 426 U.S. at 448-449)). Reports of adverse events that lack any statistical significance are exactly the type of speculative data that the materiality requirement should filter from the marketplace.

Indeed, subjecting biotechnology companies to liability for failing to disclose anecdotal reports of adverse events could require amicus's members to disclose every new incidence of a possible adverse event any time that they make statements about their products. Biotechnology companies are constantly asked, and constantly make statements, about products that are in development, being tested, or on the market—not only in public filings, but also in press releases, television appearances, investor

calls, and the like. This is especially true for companies, like petitioner, with few (or even just a single) widely-used products. Since adverse event reports are ubiquitous, these companies would be making constant disclosures of possible adverse events. This barrage of immaterial information on the investing public is not the type of disclosure that federal securities laws require.

2. *There can be no "strong inference" of scienter if the defendant failed only to disclose statistically insignificant data*

The Ninth Circuit's decision also subjects amicus's members to potential liability for securities fraud without evidence or allegations of intent to deceive or defraud.

a. To establish liability under Section 10(b) and Rule 10b-5, a plaintiff must prove not only that the alleged misstatement or omission was material but that the defendant made the misstatement or omission with scienter, i.e., intent to deceive, manipulate, or defraud. *Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 193 (1976). Thus, in a Section 10(b) lawsuit, the plaintiff must show that, at the time of the alleged non-disclosure of adverse events, the drug manufacturer intended to deceive investors into believing that the adverse events were not caused by the drug.

But such a defendant cannot have acted with the requisite scienter unless the incidence of adverse events was statistically significant. "A statement

cannot be intentionally misleading if the defendant did not have sufficient information at the relevant time to form an evaluation that there was a need to disclose certain information and to form an intent not to disclose it." *New Jersey Carpenters Pension & Annuity Funds v. Biogen Idec Inc.*, 537 F.3d 35, 45 (1st Cir. 2008). Thus, a drug manufacturer cannot have committed fraud if it did not know that not disclosing them would be misleading. *Id.* at 48. And a drug manufacturer cannot have had sufficient evidence to subjectively understand that not disclosing adverse events would be misleading in the context of statements about its products or earnings unless the incidence was statistically significant and a causal relationship could be inferred from it.

b. Moreover, unless the complaint alleges that the defendant was aware of not just isolated adverse events but statistically significant events, the complaint cannot satisfy the pleading requirements of the Private Securities Litigation Reform Act of 1995 ("PSLRA"). The PSLRA requires securities fraud plaintiffs to plead "with particularity facts giving rise to a strong inference that the defendant acted with" scienter. 15 U.S.C. § 78u-4(b)(2). A complaint that alleges facts that create merely a possibility of scienter, as opposed to a "strong inference" of scienter, must be dismissed.

This Court has held that "in determining whether the pleaded facts give rise to a 'strong' inference of scienter, the court must take into account plausible opposing inferences." *Tellabs, Inc. v. Makor Issues &*

Rights, Ltd., 551 U.S. 308, 323 (2007). That is, "plausible[,] nonculpable explanations for the defendant's conduct" must be considered, in addition to inferences favoring the plaintiff. *Id.* at 324. "[T]he inference of scienter must be more than merely 'reasonable' or 'permissible'—it must be cogent and compelling, thus strong in light of other explanations." *Ibid.* A complaint will survive a motion to dismiss "only if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *Ibid.*

Where the complaint's only allegations of scienter are that the defendant was aware of isolated reports of adverse effects, but that those reports do not amount to statistically significant occurrences, that does not give rise to the requisite "strong inference" of scienter. Indeed, "no plausible inference" may be drawn from reports that are not statistically significant because they establish no causal relationship between the adverse events and use of the drug. *New Jersey Carpenters Pension*, 537 F.3d at 50. For the same reason that reports of isolated adverse events are not required to avoid making statements materially misleading to a reasonable investor, a biotechnology defendant would likewise not find such reports to be significant to its drug's safety or commercial viability. Moreover, because it is reasonable for a company, given its experience and prevailing wisdom, to conclude that such adverse event reports are not material, it would not be plausible to conclude that it

had an intent to defraud the market, rather than that it simply did not disclose information that it thought was not scientifically relevant. *See City of Philadelphia v. Fleming Cos.*, 264 F.3d 1245, 1261 (10th Cir. 2001) (to establish scienter in securities fraud action, plaintiff must prove not only that defendant knew of allegedly omitted fact but also that "failure to reveal the potentially material fact would likely mislead investors"). Thus, the pleading of such isolated reports, without more, does nothing to advance an inference of scienter, much less a strong inference.

To hold otherwise would effectively gut the gatekeeping function of the PSLRA as it relates to public companies whose drugs become the subject of safety concerns. If a plaintiff can state a claim simply by alleging that a drug manufacturer failed to disclose statistically insignificant events, plaintiffs will almost always be able to state a claim, because reports of such adverse events will always precede statistically meaningful information or even the ability of drug safety professionals to detect a meaningful safety signal. But the converse is not true: adverse events are not always followed by statistically significant information or detectable safety signals. Companies therefore should not be subject to liability for securities fraud for making statements about their products or earnings without disclosing such statistically insignificant events. If the Ninth Circuit's decision is left standing, a securities plaintiff will be able to survive the pleadings stage, and potentially get to the jury, on claims based on drug safety simply

by alleging the failure to disclose a meaningless adverse event—an allegation a plaintiff almost certainly will be able to make.

CONCLUSION

For the reasons set forth above and in petitioners' brief, the judgment should be reversed.

Respectfully submitted,

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Supreme Court of the United States

MATRIXX INITIATIVES INC., ET AL.,

Petitioners,

v.

JAMES SIRACUSANO AND NECA-IBEW PENSION FUND,

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

BRIEF FOR THE CONSUMER HEALTHCARE PRODUCTS ASSOCIATION AND THE COUNCIL FOR RESPONSIBLE NUTRITION AS *AMICI CURIAE* IN SUPPORT OF PETITIONERS

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INTEREST OF AMICI CURIAE

The Consumer Healthcare Products Association (CHPA) is the not-for-profit association representing the makers of over-the-counter (OTC) medicines and nutritional supplements and the consumers who rely on these healthcare products.[1] CHPA is one of the oldest trade associations in the United States. It has more than 70 active members that manufacture or market OTC medicines and nutritional supplements, as well more than 120 associate members that provide goods and services to the active members. CHPA is committed to promoting the increasingly vital role of OTC medicines and nutritional supplements in America's healthcare system through science, education, and advocacy. Among its many activities, CHPA shares information with partners across the globe to promote the safe and responsible use of OTC medicines. CHPA also monitors legal issues that affect its members, as well as the entire industry, and offers its perspectives in cases that raise such issues.

The Council for Responsible Nutrition (CRN) is the leading trade association representing dietary supplement manufacturers and ingredient suppliers. CRN has more than 70 members that produce a large portion of the dietary supplements marketed in

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[1] Pursuant to Rule 37.6, *amici* confirm that no counsel for a party authored this brief in whole or in part, and no party or counsel for a party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than *amici* made a monetary contribution to its preparation or submission. The parties have consented in writing to the filing of this brief.

the United States and around the world. CRN members manufacture popular national brands; store brands marketed by major supermarkets, drug stores, and discount chains; and products marketed through natural food stores and mainstream direct selling companies. In addition to complying with federal and state regulations governing dietary supplements, CRN members adhere to voluntary guidelines for manufacturing and marketing and CRN's Code of Ethics.

This case presents the question whether a plaintiff can state a claim under § 10(b) of the Securities Exchange Act and SEC Rule 10b-5 based on a company's nondisclosure of adverse event reports even if the complaint contains no allegation that the reported adverse events are statistically significant. That issue is important to the many CHPA and CRN members that are, or may become, publicly traded companies. Because hundreds of thousands of adverse events are reported each year, the Ninth Circuit's approach could lead to a flood of securities litigation. A company could protect itself from such litigation by disclosing all adverse event reports in its securities filings, even if there is no evidence that the adverse events are causally related to the company's product. But such undifferentiated disclosures would not be useful to investors, and would make it more difficult to identify meaningful information about adverse events associated with a company's products. Undifferentiated disclosures also could prompt consumers and health care providers to stop using a product based on unsubstantiated concerns about adverse event

reports while obscuring important, validated adverse event information.

SUMMARY OF ARGUMENT

1. Adverse event reports play an essential role in identifying potential safety issues with OTC medicines and dietary supplements, but they have significant limitations. Most importantly, adverse event reports, standing alone, do not establish a causal relationship between a product and an adverse event. Adverse events may occur for a variety of reasons that are unrelated to the product. Moreover, adverse event reports are of variable quality and are often incomplete. Because consumers are permitted to use OTC medicines and dietary supplements without the supervision of a physician, adverse event reports for these products are more likely to be submitted by consumers, and may be less informative and medically precise than adverse event reports submitted by health care providers.

2. To determine whether adverse event reports suggest a causal association between an adverse event and a product, it is necessary to analyze the adverse event data. A wide range of factors may be relevant to this analysis, including the frequency of the adverse event among consumers who are using the product and the frequency of the adverse event among consumers who are *not* using the product. Even after careful analysis of adverse event reports, it may be necessary to conduct additional studies to assess whether there is a causal relationship between an adverse event and a product. The U.S. Food and Drug Administration's internal process for determining whether to act on adverse event reports

confirms that inferences of causation must be based on careful analysis of the data.

3. The statistical significance standard recognized by most courts of appeals appropriately recognizes that adverse event reports, standing alone, are not "material" for purposes of federal securities laws. The statistical significance standard addresses the quality of the evidence of a relationship between an adverse event and a product, and therefore it is not the kind of "bright-line" rule that this Court rejected in *Basic Inc. v. Levinson*, 485 U.S. 224 (1988).

4. The Ninth Circuit's rejection of a statistical significance standard is detrimental to investors and consumers. Under the Ninth Circuit's standard, companies have an incentive to disclose all adverse event reports without regard to whether there is any evidence of a causal connection between the adverse event and the product. As a result, the Ninth Circuit's approach is likely to bury investors "in an avalanche of trivial information – a result that is hardly conducive to informed decisionmaking." *Basic*, 485 U.S. at 231 (citation and internal quotation marks omitted). In the analogous context of warnings in prescription drug labeling, the Food and Drug Administration has recognized that "overwarning" has the effect of not warning at all, because the reader stops paying attention to excess warnings. Undifferentiated disclosures also could cause consumers to stop using beneficial medications based on unfounded concerns based on adverse event reports, and could decrease appropriate responses to real safety issues.

ARGUMENT

I. Adverse Event Reports Do Not Establish A Causal Relationship Between An Adverse Event And A Product.

In order to understand the issue in this case, it is necessary to understand the nature and limitations of adverse event reports. Spontaneous adverse event reporting by health care providers (HCPs) and consumers is entirely voluntary. The U.S. Food and Drug Administration (FDA) encourages consumers and HCPs to report adverse events directly to FDA through its MedWatch program, and provides a form, Form 3500, to gather information about adverse events.[2] Although the form requests a wide range of information, adverse event reports are of variable quality and are often incomplete.[3]

Instead of, or in addition to, reporting an adverse event to FDA, consumers and HCPs may report adverse events to the manufacturer, packer, or

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[2] *See* Form 3500, *available at* http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm. Reports can be submitted online (at www.fda.gov/medwatch), by telephone (1-800-FDA-1088), by fax (1-800-FDA-0178), or by regular mail.

[3] Form 3500 requests information about: the patient (e.g., age, gender, weight), the adverse event (e.g., type of event, outcomes attributed to the adverse event, dates of the event and the report, description of the event, relevant tests/laboratory data, other relevant clinical history); the suspect product(s) (e.g., name, strength, and manufacturer, dosage, frequency and route of administration; dates of use; diagnosis or reason for use; whether the event abated after the dose was stopped or reduced; whether the event reappeared after reintroduction); and other medical products used and dates of use.

distributor listed on the label of the product. In turn, that entity has obligations to report some adverse events to FDA.[4] For non-prescription products such as the product at issue in this case, and for dietary supplements, the entity's reporting obligations depend on how the product is regulated.[5]

For an OTC drug that is marketed under a monograph, a homeopathic drug, or a dietary supplement, the manufacturer, packer, or distributor whose name appears on the label (the "responsible person") must report to FDA all serious adverse events associated with the product when used in the United States, whether or not the responsible person believes the events are related to the product. Federal Food, Drug, and Cosmetic Act (FDCA) §§ 760(b)(1), 761(b)(1), 21 U.S.C. §§ 379aa(b)(1), 379aa-1(b)(1). A "serious adverse event" is defined as an adverse event that results in death, a life-threatening experience, inpatient hospitalization, persistent or significant disability or incapacity, or congenital anomaly or birth defect; or that requires,

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[4] A reportable adverse event may include, in addition to a side effect of a product, an occurrence due to an accidental overdose, abuse, withdrawal, or failure of expected pharmacologic action. Federal Food, Drug, and Cosmetic Act (FDCA) §§ 760(a)(1), 761(a)(1), 21 U.S.C. §§ 379aa(a)(1), 379aa-1(a)(1).

[5] Most OTC drug products are marketed under an OTC monograph that specifies the conditions under which a drug product is considered to be generally recognized as safe and effective. Other OTC drug products (including some drug products that previously were marketed as prescription drugs, such as ibuprofen) are marketed based on new drug applications that FDA reviewed and approved prior to market entry.

based on reasonable medical judgment, a medical or surgical intervention to prevent one of these outcomes. FDCA §§ 760(a)(3), 761(a)(2), 21 U.S.C. §§ 379aa(a)(3), 379aa-1(a)(2). The responsible person must report serious adverse events within 15 business days and submit certain new medical information related to a submitted serious adverse event report within 15 business days of receiving the new information.[6] Non-serious adverse events need not be reported to FDA, but the responsible person must maintain records of all adverse event reports, subject to inspection by FDA, for six years. FDCA §§ 760(e), 761(e), 21 U.S.C. §§ 379aa(e), 379aa-1(e).[7]

Congress clearly understood that an adverse event report does not necessarily indicate a causal relationship between a product and an adverse event. The FDCA expressly provides that submission of any adverse event report shall not be construed as an admission that the product caused or contributed to the adverse event. FDCA §§ 760(g), 761(g), 21 U.S.C. §§ 379aa(g), 379aa-1(g). The legislative history of the FDCA states emphatically: "The committee emphasizes that adverse events are communicated from consumers regarding events that

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[6] This reporting requirement for new medical information applies to information that the responsible person receives within one year of the initial report. FDCA §§ 760(c), 761(c), 21 U.S.C. §§ 379aa(c), 379aa-1(c).

[7] Congress recognized that a broader reporting requirement would be counterproductive: "[A]ny broader reporting system could overburden manufacturers, consumers, and the agency alike, generating information that may not be useful to the public health system at tremendous cost to all involved." S. Rep. No. 109-324 at 6 (2006).

may be associated with the use of a dietary supplement or nonprescription drug. The fact of a report of an adverse event is not determinative that the event occurred or that the event was caused by a consumer's use of the product." S. Rep. No. 109-324 at 6 (2006).

The reporting requirements for an OTC drug marketed under a new drug application (NDA) are somewhat broader. If a serious adverse drug experience is unexpected (i.e., not in the current labeling for the product), the NDA holder ("applicant") must submit an "alert report" to FDA as soon as possible, but within 15 calendar days.[8] The applicant also must submit follow-up reports within 15 calendar days of receiving new information or as requested by FDA. 21 C.F.R. § 314.80(c)(1). These requirements apply whether the serious and unexpected adverse drug experience is domestic or foreign. Adverse drug experiences that are not required to be reported as 15-day alert reports must be included in periodic reports to FDA.[9]

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[8] An adverse drug experience is "[a]ny adverse event associated with the use of a drug in humans, *whether or not considered drug related*," including adverse events occurring in the course of the use of a drug product in professional practice or from overdose (whether accidental or intentional), abuse or withdrawal, or failure of expected pharmacological action. 21 C.F.R. § 314.80(a) (emphasis added).

[9] These periodic reports are required at quarterly intervals for three years from the date of approval of the NDA, and at annual intervals thereafter, except that FDA may upon written notice require that the applicant submit reports at different intervals. 21 C.F.R. § 314.80(c)(2).

Although adverse event reports play an essential role in identifying potential safety issues, they have significant limitations.[10] Most importantly, adverse event reports, standing alone, do not establish a causal relationship between the adverse event and the product. Adverse events can occur for a variety of reasons that are unrelated to the product. For example, an adverse event could be a manifestation of a patient's underlying health condition or a side effect of another medication that a consumer is taking. At a recent meeting convened by the Institute of Medicine, a senior FDA official noted, "The main question is: is there a causal association? Many results from such signals will not be replicated by additional research; some will."[11]

An additional limitation of adverse event reports is that the number of reports does not reflect the actual frequency of the event. Raw adverse event data are not gathered in any systematic fashion. Instead, they are the result of spontaneous, voluntary reports. The rate at which adverse events

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[10] *See, e.g.*, Lanh Green, Pharm.D., M.P.H., Office of Surveillance and Epidemiology, Center for Drug Evaluation and Research, FDA, *Postmarketing Pharmacovigilance Practice at FDA*, presented at Drug Information Association 42nd Annual Meeting, Slide 9 (June 21, 2006), *available at* http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/ucm119101.pdf.

[11] Janet Woodcock, M.D., Director, CDER, FDA, *Studying the Safety of Marketed Drugs: Ethical and Design Issues*, presented at the first meeting of the Committee on Ethical and Scientific Issues in Studying the Safety of Approved Drugs, Slide 2 (June 7, 2010), *available at* http://www.iom.edu/~/media/Files/Activity%20Files/Quality/DrugSafetyPostMarket/2010-JUN-07/Woodcock.ashx.

are reported has been shown to depend on many factors, including the time since product launch, safety-related regulatory activity, media attention, and the use of the product. FDA, *Guidance for Industry: ICH E2E Pharmacovigilance Planning* 11 (Apr. 2005). To further complicate matters, more than one report may be filed about the same adverse event.[12]

As a result, determining the incidence of an adverse event based on adverse event reports is not a straightforward process. In the words of an FDA official, "the numerator is uncertain" and "the denominator can only be projected."[13] The "numerator" (the number of occurrences of an adverse event among consumers taking the drug) must be estimated based on a relatively small set of adverse event reports that were collected in a non-systematic manner. The "denominator" (the number of consumers who are using a drug product) must also be estimated, because product sales data do not necessarily equate to product use.[14]

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[12] Green, *supra* note 10, Slide 9.

[13] *Id.*

[14] FDA, *FDA Transparency Initiative: Draft Proposals for Public Comment Regarding Disclosure Policies of the U.S. Food and Drug Administration* (May 2010) at 18. Adverse events that occur in the context of clinical trials — rather than in general use — are collected and analyzed more systematically, and companies report these adverse events to FDA under a separate reporting system. These types of adverse events are distinct from the spontaneous adverse event reports that are at issue in this case.

Still another limitation of adverse event reports is that they are often incomplete. As an FDA drug safety official has noted, "one of the limitations of spontaneous reports is that, in general, they are poorly documented, and the evaluator may need to contact the event reporter . . . in order to secure follow-up information."[15] FDA Guidance advises caution in interpreting adverse event reports because the data accompanying them are often incomplete.[16]

The limitations of adverse event reports are particularly pertinent for non-prescription products and dietary supplements. Because consumers are permitted to use these products without the supervision of a physician or other HCP, adverse events reports for these products are more likely to be submitted by consumers rather than HCPs. A consumer's adverse event report may be less informative than an HCP's report. For example, the description of the adverse event may not be as medically precise as the one that an HCP would give, and a consumer may not provide the relevant

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[15] Syed Ahmad, M.D., M.P.H., Division of Drug Risk Evaluation, Office of Drug Safety, Center for Drug Evaluation and Research, FDA, *Adverse Drug Event Monitoring at the FDA*, 18 J. Gen'l Internal Medicine 57, 58 (2003).

[16] FDA, *Guidance for Industry: ICH E2E Pharmacovigilance Planning* 11 (Apr. 2005); Adverse Event Reporting System description, *available at* http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/default.htm. The Adverse Event Reporting System (AERS) is a computerized information database designed to support FDA's post-marketing safety surveillance program for all approved drug and therapeutic biologic products. FDA uses AERS to monitor for new adverse events and medication errors that might occur with these marketed products.

medical history that would help put the adverse event in context.

In sum, adverse event reports are important and useful, but they have significant limitations. Standing alone, adverse event reports do not establish a causal relationship between an adverse event and a product.

II. Adverse Event Data Must Be Analyzed To Determine Whether An Adverse Event Is Causally Related To A Product.

To determine whether adverse event reports suggest a causal association between an adverse event and a product, it is necessary to analyze the raw adverse event data. A wide range of factors may be relevant to the analysis, including:

- The temporal relationship between exposure to the product and the adverse event,
- The clinical and pathological characteristics of the event,
- Whether there is a plausible biological or pharmacologic mechanism that could account for the adverse event,
- Whether the event or related event has been reported previously for the product or a related product,
- Whether other medication(s) taken at the same time or prior to the product could have caused the event,
- Whether an underlying condition could have caused the event,

- Whether the adverse event subsides when the product is stopped or reduced in dosage,
- Whether the adverse event reappears when the product is re-introduced or the dosage is increased,
- The frequency of the adverse event among consumers who are using the product, and
- The frequency of the adverse event among consumers using the product, compared to the frequency of the adverse event among similar consumers who are not using the product.

See generally Stephens' Detection of New Adverse Drug Reactions 331-34 (John Talbot & Patrick Walker eds., 5th ed. 2004).

A number of analytical techniques may be useful to assess potential causality from adverse event reports, including unrestricted evaluation/global introspection, structured algorithms, and Bayesian probabilistic analysis. *See id.* at 337.

Even after careful analysis of adverse event reports, it may be unclear whether there is a relationship between a product and an adverse event. In such cases, it may be necessary to conduct additional studies that are designed specifically to assess the potential relationship.

> If the cases are scanty and most are associated with reasonable alternative explanations, then a watching brief is likely to be the most appropriate course. At the other extreme, a well-documented series of cases of a particular suspected [adverse drug

> reaction] without obvious alternative explanation and/or with evidence of a possible mechanism should rapidly lead to consideration of both what further investigation may be warranted and what action is needed to minimize the risks. Many issues come between these extremes, and this requires careful consideration of evidence from various sources and of the possible ways in which any issue might be investigated further.

Id. at 354.

As additional data become available (for example, from specifically designed studies or other pertinent sources, such as the medical literature), these data can be considered in the context of the previously available adverse event data. Assessing evidence from multiple sources of information can be complex. A commonly-used framework for this type of assessment, known as the Bradford-Hill criteria, considers a range of factors: strength, consistency, specificity, temporality, biological gradient, plausibility, coherence, experimental evidence, and analogy.[17]

FDA's internal process for determining whether to act on adverse event reports reflects the need for careful analysis of the data as a basis for drawing inferences of causation. As described above, FDA

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[17] For a brief explanation of the Bradford-Hill criteria, *see Stephens' Detection of New Adverse Drug Reactions* at 338-39.

receives adverse event information from two primary sources: voluntary adverse event reports submitted by HCPs and consumers, and mandatory adverse event reports from responsible parties. Clinical reviewers at FDA evaluate the adverse event reports. If the reviewers identify a potential safety concern — often referred to as a "safety signal" — they will search for additional, related events in the Adverse Event Reporting System (AERS) or the medical literature, and may check with foreign regulatory agencies to determine whether they can discern a common trend, causal relationship, or pattern of events. A reviewer may look for indicators such as a temporal association (i.e., the product was taken before the adverse event), consistency with existing information or biological plausibility, a similar event in products of the same class, dose-response relationships, and the specificity and consistency of the association.

If the safety signal appears to be real, FDA may take steps to confirm it, including epidemiologic studies in large databases that link prescriptions with adverse outcomes, queries to foreign regulatory agencies about whether similar adverse events have been reported to them, and/or analyses of a World Health Organization database that collects adverse drug reactions data from over 60 countries. *See* Ahmad, *supra* note 15, 58.

Based on its further evaluation of the potential safety signal, FDA may take a range of actions to inform consumers and HCPs and protect the public health. FDA's course of action depends on the strength of the evidence linking an adverse event to a particular product. For example:

- On a quarterly basis, FDA publishes Potential Signals of Serious Risks/New Safety Information Identified by the Adverse Event Reporting System (AERS).[18] In this publication, FDA is careful to note that although it has identified a potential safety issue, it has not necessarily identified a causal relationship between the drug and the listed risk: "[i]f, after further evaluation, FDA determines that the drug is associated with the risk, it may take a variety of actions including requiring changes to the labeling of the drug, . . . or gathering additional data to better characterize the risk . . . FDA will complete its evaluation of each potential signal/new safety information and issue additional public communications as appropriate."

- FDA also publishes Drug Safety Communications that alert the public to important safety information,[19] including situations in which FDA is continuing to review new information to evaluate the

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[18] Potential Signals of Serious Risks/New Safety Information Identified by the Adverse Event Reporting System, *available at* http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm216272.htm.

[19] Drug Safety Communications, *available at* http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm199082.htm. These communications are also indexed by drug product. *See* Index to Drug-Specific Information, *available at* http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm111085.htm.

relationship between reported adverse events and a product, and where FDA recommends that HCPs and patients continue to use the medications according to the recommendations in the label.[20]

- Where there is more convincing evidence of an association between an adverse event and a product, FDA may require updates to a product's labeling information, restrict use of the product, issue communications to HCPs and/or consumers, and in the most compelling instances, remove the product from the market.

Even after rigorous evaluation and analysis of adverse event reports and other efforts — including additional studies — to confirm whether a signal is "real," it is not always clear whether there is a causal association between a product and an adverse event. Indeed, a senior FDA official noted at a recent Institute of Medicine meeting that the biomedical community "lack[s] a consensus on the quantity and quality of data that . . . convincing[ly]" shows a causal association.[21]

The example of calcium channel blockers (CCBs) demonstrates that initial signals can prove to be illusory. CCBs are prescription drugs used to treat

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[20] *See, e.g.*, FDA Drug Safety Communication: Ongoing safety review of oral biphosphonates and atypical subtrochantic femur fractures, *available at* http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm203891.htm

[21] Woodcock, *supra* note 11, Slide 2.

high blood pressure and other cardiovascular indications. In the mid-1990s, a series of epidemiologic studies suggested that CCBs could be associated with serious adverse events, including heart attacks, death, cancer, and suicide. A subsequent series of epidemiologic studies in the late-1990s found no increased risk of these same adverse events. Ultimately, in large randomized, controlled trials that were designed to test specifically for these adverse events, these events were not observed.

III. Requiring Plaintiffs To Plead Statistical Significance Reflects The Reality That Adverse Event Reports, Standing Alone, Do Not Indicate A Causal Relationship.

As described above, epidemiologists and regulators do not take a collection of adverse event reports at face value. Recognizing the limitations of raw adverse event data, they analyze the reports, and frequently seek additional information, to determine whether there is a relationship between the adverse event and the product.

The statistical significance standard established in *Carter-Wallace I and II* recognizes that raw adverse event reports, standing alone, are not material: "Drug companies need not disclose isolated reports of illnesses suffered by users of their drugs until those reports provide statistically significant evidence that the ill effects may be caused by — rather than randomly associated with — use of the drugs and are sufficiently serious and frequent to affect future earnings." *In re Carter-Wallace, Inc., Sec. Litig.*, 150 F.3d 153, 157 (2d Cir. 1999) ("*Carter Wallace I*"). This standard requires the plaintiff to

allege that there is sufficient evidence, based on appropriate analysis, that there may be a causal association between a product and an adverse event, such that the adverse event would be material information to the reasonable investor. Without evidence of a statistically significant association between a product and an adverse event, a plaintiff cannot reasonably allege that a company (or its officers or directors) failed to disclose an adverse event with the requisite scienter, because the company did not have reason to regard the adverse event as material.

Contrary to the Ninth Circuit's suggestion, the statistical significance requirement is not a "bright-line" rule of the kind that this Court rejected in *Basic Inc. v. Levinson*, 485 U.S. 224 (1988). In *Basic*, the Court rejected an argument that the existence of preliminary merger discussions is not material information until the parties have reached an agreement-in-principle, noting that "[a]ny approach that designates a single fact or occurrence as always determinative of an inherently fact-specific finding such as materiality must necessarily be overinclusive or under-inclusive." *Id.* at 236.

Respondents' assertion that the statistical significance standard is a "bright-line rule" of the type rejected in *Basic* mischaracterizes the statistical significance standard. That standard does not adopt any pre-determined metric, such as a fixed number of adverse events. As *Carter-Wallace II* made clear, the statistical significance standard does not rely on specific numbers, but instead on the quality of the evidence of a relationship between the adverse event and the drug:

> The complaint describes the adverse reports received by Carter-Wallace and concludes that the 'adverse events . . . were extremely serious and the number of incidences was . . .statistically unacceptable.' This allegation is based, like much of the appellants' arguments, on the sheer number of adverse reports — 57 — before July 1994.
>
> We do not believe that the existence or the number of such reports is problematic . . . [T]he receipt of an adverse report does not in and of itself show a causal relationship . . . Some adverse events may be expected to occur randomly, especially with a drug designed to treat people that are already ill.

In re Carter-Wallace, Inc., Sec. Litig., 220 F.3d 36, 40-41 (2d. Cir. 2000) ("*Carter-Wallace II*").

As described above, the analytic process for evaluating whether there is a relationship between an adverse event and a product is fact-specific. The process involves numerical analysis, but it also involves complex medical judgments based on a relatively small number of adverse event reports that are often incomplete and of uneven quality, weighing evidence from multiple sources of information, and assessing the totality of available data against multiple criteria. This process is not properly characterized as a "bright-line rule." Instead, the statistical significance standard distinguishes complaints that allege only the existence of some number of adverse event reports from complaints

that allege sufficient evidence, based on appropriate analysis and other pertinent information, of a causal association between that product and an adverse event.

IV. The Ninth Circuit's Approach Is Detrimental To Investors And Consumers.

FDA received almost 600,000 adverse event reports in 2009. Based on the number received in the first quarter of 2010, it is likely to receive more than 600,000 reports this year.[22] Under the Ninth Circuit's approach, a plaintiff can allege a violation of Section 10(b) and Rule 10b-5 merely by alleging that the defendant failed to disclose some number of adverse event reports. Such a permissive pleading standard could lead to a flood of meritless securities litigation. Unless plaintiffs are required to allege a statistically significant link between a product and adverse events, claims based on randomly associated adverse events will be permitted to proceed to discovery.[23] As this Court has recognized, discovery

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[22] Reports Received and Reports Entered into AERS by Year, *available at* http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm070434.htm.

[23] The district court in *In re Pfizer Inc. Securities Litigation*, 584 F.Supp.2d 621 (S.D.N.Y. 2008), like the Ninth Circuit in *Matrixx*, refused to require statistical significance as a threshold for materiality at the motion to dismiss stage. The court determined that statistical significance was a fact issue for the jury. *Id.* at 635-36. The court thus left the issue of materiality for determination at summary judgment. As a result, Pfizer has been forced to expend millions of dollars to conduct discovery and defend the case.

costs alone create significant pressure to settle even meritless claims, particularly in class action litigation. *See, e.g., Dura Pharm., Inc. v Broudo*, 544 U.S. 336, 347 (2005).

Companies faced with an onslaught of securities litigation under the Ninth Circuit's standard have an incentive to disclose *all* adverse event reports, without regard to whether there is any evidence of a causal connection between the adverse event and the product. Such an undifferentiated listing of all adverse events that occurred during a securities filing period will defeat the purpose of the materiality standard by burying meaningful information in an avalanche of essentially meaningless information. This Court's concern about inundating investors with too much information was the basis for the materiality standard articulated in *TSC Industries* and adopted in *Basic*: "[T]he Court was careful not to set too low a standard of materiality; it was concerned that a minimal standard might bring an overabundance of information within its reach, and lead management 'simply to bury the shareholders in an avalanche of trivial information — a result that is hardly conducive to informed decisionmaking.'" *Basic*, 485 U.S. at 232 (citing *TSC Indus., Inc. v. Northway, Inc.*, 426 U.S. 438, 448-49 (1976)).

The detrimental effect of an overinclusive listing of adverse events has been recognized in the analogous context of warnings in prescription drug labeling. To reduce exposure to tort liability based on failure to warn, prescription drug companies have an incentive to include a broad set of warnings in labeling, even if some of those warnings have not

been scientifically established. When labeling includes too many warnings, however, the warnings tend to lose their effectiveness. As FDA has recognized, "[o]verwarning has the effect of not warning at all. The reader stops paying attention to excess warnings."[24] Research on risk communication underscores the importance of limiting disclosures to significant information, since "extraneous information distracts" and "erodes ability to remember key points."[25]

Undifferentiated disclosure of adverse events may also be harmful to consumers. As a result of such disclosures, consumers might stop taking beneficial medications based on concerns about adverse events that are unrelated to the medications. FDA officials have raised this concern in connection with its proposal to disclose more adverse events information to the public. As a senior FDA official noted, disclosure of adverse events without appropriate context can harm public health because patients and HCPs may overreact to potential safety signals (e.g.,

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[24] Center for Devices and Radiological Health, FDA, *Write it Right: Recommendations for Developing User Instruction Manuals for Medical Devices Used in Home Health Care* 7 (1993), *available at* http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070771.pdf

[25] Kala L. Paul, M.D., *Learnings from Consumer Research in Risk Communication*, presented at FDA hearing on Medication Guides, Slide 12 (June 12-13, 2007), *available at* http://www.fda.gov/downloads/Drugs/DrugSafety/UCM173468.pdf.

by stopping their medicines).[26] In addition, the FDA official warned that patients and HCPs could become desensitized to safety information: "[O]ver-response to eventual false positives will cause unnecessary concern and drug cessation [and] potentially decrease appropriate responses to real safety issues in the future."[27]

For each of these reasons, the Ninth Circuit erred in rejecting the statistical significance requirement adopted by other federal courts of appeals.

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[26] *FDA Seeks IOM's Help in Setting Threshold for Post-Market Drug Safety Action*, FDA Week (June 22, 2010). FDA proposes to address this concern by accompanying adverse event data with a clear disclaimer to ensure that concerns associated with disclosure of adverse event data do not override the benefits of those disclosures.

[27] Woodcock, *supra* note 11, Slide 4.

CONCLUSION

The decision of the Ninth Circuit should be reversed.

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AMICUS CURIAE BRIEF

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Petitioners,

v.

JAMES SIRACUSANO AND NECA-IBEW PENSION FUND,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

BRIEF OF DRI—THE VOICE OF THE DEFENSE BAR AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

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INTEREST OF *AMICUS CURIAE* [1]

Amicus curiae DRI—The Voice Of The Defense Bar is an international organization of more than 22,000 attorneys who often represent individual and corporate defendants in civil cases carrying significant costs and liability exposure. Because of their adverse business and economic impacts, DRI and its members have a vital interest in the fair, efficient, and consistent functioning of our justice system in such cases.

DRI members regularly defend securities fraud suits brought under § 10(b) of the Securities Exchange Act of 1934, 15 U.S.C. § 78j(b), and SEC Rule 10b-5, 17 C.F.R. § 240.10b-5. Plaintiffs in these fraud suits are required to plead and prove that defendants' alleged misrepresentations or omissions concern a "material" fact. Under this Court's precedents, this "materiality" requirement acts as a filter on the information that public companies must disclose and helps ensure informed investment decisions by compelling disclosure only of reliable information related to a company's operations or its products.

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[1] No party or counsel for a party authored any part of this brief, and no person or entity other than *amicus*, its members, or its counsel made a monetary contribution intended to fund the preparation or submission of the brief. The parties have consented to the filing of this brief.

Here, the Ninth Circuit's decision compelling disclosure of anecdotal adverse event reports by companies that manufacture pharmaceuticals or medical devices conflicts with this Court's materiality precedents, undercuts the materiality requirement's filtering function, and thwarts this Court's expressed interest in ensuring "informed decisionmaking" by investors. *See TSC Indus., Inc. v. Northway, Inc.*, 426 U.S. 438, 449 (1976); *Basic Inc. v. Levinson*, 485 U.S. 224, 231 (1988).

Moreover, in evaluating the legal sufficiency of respondents' complaint, the Ninth Circuit effectively immunized materiality allegations from the scrutiny demanded by this Court's precedents in *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007) and *Ashcroft v. Iqbal*, 129 S.Ct. 1937 (2009). That immunization, in turn, severely impedes the district courts' ability to screen meritless securities fraud suits.

Finally, although not apparent from the Ninth Circuit's holding or reasoning, the compelled disclosure of anecdotal adverse event reports also unnecessarily threatens the regulation and use of pharmaceuticals and medical devices. Yet, given the life-enhancing and life-sustaining quality of these products, such threats should be avoided, not fostered, by legal standards implemented under the securities laws.

In short, the Ninth Circuit's decision has a profound effect on companies who must publicly disclose material information under the securities laws and unsettles the existing law governing securities cases in significant and undesirable ways. Those impacts directly affect the fair, efficient, and consistent functioning of our civil justice system and, as such, are of vital interest to DRI and its members. DRI therefore respectfully offers its views on the proper resolution of the issues raised in this case.

SUMMARY OF ARGUMENT

This case requires the Court to interpret the requirement under § 10(b) and Rule 10b-5 that plaintiffs must plead a misrepresentation or omission of "material" fact in order to survive a motion to dismiss. Specifically, this case requires the Court to decide whether a statistically insignificant number of reports of adverse patient reactions *hypothetically* linked to the use of a pharmaceutical or medical device are "material" facts that must be disclosed in order to avoid liability under § 10(b). The Court should conclude that in this case, these random adverse event reports ***cannot*** plausibly be equated with those "material" facts that must be disclosed under § 10(b) and Rule 10b-5.

Congress passed the federal securities laws to "protect investors" in publicly-traded companies. *Basic*, 485 U.S. at 230 (citing S. Rep. No. 792, 73d

Cong., 2d Sess., 1-5 (1934)); *Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 195 (1976). The securities laws accomplish this goal in part by establishing "materiality" requirements that compel public companies to disclose truthful and reliable information about themselves, their operations, and their products and services that very likely would affect an investor's decision whether to purchase the companies' stock. The disclosure of this truthful and reliable information enables reasonable investors to make "informed investment decisions." *Pinter v. Dahl*, 486 U.S. 622, 638 (1988) (1933 Securities Act) (citing *Securities & Exchange Comm'n v. Ralston Purina Co.*, 346 U.S. 119, 124 (1953)); *Basic*, 485 U.S. at 231 ("informed decisionmaking" ensured by Exchange Act); *cf. United States v. O'Hagan*, 521 U.S. 642, 668 (1997) ("very purpose" of Congress's 1968 amendments to Exchange Act was to ensure "informed decisionmaking" by shareholders) (citation omitted). The failure to make all such material disclosures as required by the securities laws can result in civil and even criminal liability. *See Stoneridge Inv. Partners, LLC v. Scientific-Atlanta, Inc.*, 552 U.S. 148, 166 (2008); 15 U.S.C. § 78ff, § 32(a).

In this case, the Ninth Circuit held that a public company's failure to disclose a handful of anecdotal adverse event reports involving its pharmaceutical left it open to liability under the federal securities laws. This holding—which

effectively treats all adverse event reports as potentially "material" and thus subject to disclosure—squarely conflicts with this Court's materiality precedents and Congress's avowed purpose to ensure "informed decisionmaking." This Court's precedents direct that a fact is material only if it would "significantly alter[ ] the 'total mix' of information made available" and thus would be "substantial[ly] like[ly]" to influence the investment decision of a "reasonable investor." *TSC*, 426 U.S. at 448-49; *Basic*, 485 U.S. at 231-32. Requiring disclosure of a few anecdotal reports that do not reliably indicate any causal relationship between a product and an adverse event does not further the goal of putting reliable information in the hands of a reasonable investor. In essence and in fact, it accomplishes the opposite result.

There is more. This case involves the legal sufficiency of a pleading and therefore implicates this Court's decisions in *Twombly* and *Iqbal*. Yet, in its analysis of the sufficiency of the complaint's allegations, the Ninth Circuit elided those precedents and effectively shielded materiality allegations from the scrutiny those precedents demand. Here again, the Ninth Circuit erred. *Twombly* and *Iqbal* require a showing of a plausible entitlement to relief at the pleading stage. The kind of speculative information the Ninth Circuit ordered disclosed would not enhance or influence the decisionmaking of a reasonable investor and does not

meet the materiality threshold as a matter of law. The Ninth Circuit's decision accordingly subverts the threshold plausibility analysis, erroneously leaving the assessment of materiality in this instance to the trier of fact.

There is another way. The so-called "statistical significance" standard adopted by the First, Second and Third Circuits—decidedly unlike the Ninth Circuit's compelled blanket disclosure rule—comports more closely with this Court's conception of materiality and offers a more certain and intelligible rule for pharmaceutical and medical device companies in cases like this one. *Amicus* urges the adoption of that standard in this case.

ARGUMENT

A. The Ninth Circuit's Compelled Disclosure Of Anecdotal Adverse Event Reports Undermines The Critical Filtering Role Played By Section 10(b)'s Materiality Requirement.

1. Section 10(b)'s materiality requirement is intended to filter information disclosed by public companies to help ensure informed investment decisions.

At bottom, the federal securities laws are intended to facilitate disclosure of relevant and

reliable information to shareholders and investors. The materiality requirement in § 10(b) is critical to this goal. This requirement "filter[s] out essentially useless information that a reasonable investor would not consider significant." *Basic*, 485 U.S. at 231-32 (1988); *see also* Richard C. Sauer, *The Erosion of the Materiality Standard in the Enforcement of the Federal Securities Laws*, 62 BUS. LAW. 317, 318 (Feb. 2007) ("That all information is not created equal is recognized in the federal securities laws through the concept of 'materiality.'"). As one authoritative commentator has noted, this "filtration function is fully as important to the efficient operation of the capital markets as the elimination of false information . . ." *See* Sauer, *supra*, at 317.

This Court's materiality precedents apply this filtration function by limiting what is "material"—and thus must be disclosed—to reliable information that conceivably can benefit a shareholder or investor. As this Court explained it, "[s]ome information is of such dubious significance that insistence on its disclosure may accomplish more harm than good." *TSC*, 425 U.S. at 448. To avoid this result, in *TSC*, this Court defined materiality—not in the abstract—but in terms of what a reasonable shareholder needs to know:

> "An omitted fact is material if there is a substantial likelihood that a reasonable shareholder would consider it important in deciding how to vote."

Id. at 449. *See also id.* ("there must be a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available"). This Court further cautioned that if the materiality threshold is set too "low," management will be inclined to "bury shareholders in an avalanche of trivial information"—"a result that is hardly conducive to informed decisionmaking." *Id.* at 448-49.

The concerns that prompted this Court to steer clear of flooding shareholders with unreliable information in *TSC* prompted it to apply the same "substantial likelihood" materiality standard to § 10(b) investor claims in *Basic*. *See Basic*, 485 U.S. at 231-32. There, the Court again highlighted the adverse consequences of setting the materiality threshold too low:

> "[Setting] too low a standard of materiality . . . might bring an overabundance of information within its reach[,]" thereby inducing management to bombard investors with even "trivial information."

Id. To avoid this result and facilitate informed decisionmaking, the Court reiterated that "[t]he role of the materiality requirement is . . . to filter out essentially useless information that a reasonable

investor would not consider significant. . . " *Id.* at 234.

TSC and *Basic* clearly reflect the Court's view that the materiality requirement serves a critical filtering function. It is intended (1) to help ensure that only reliable information is conveyed to shareholders or investors and (2) to guard against swamping shareholders or investors with trivial or insignificant information that clouds informed decisionmaking.

While this filtering function is a cornerstone of this Court's materiality precedents, under the Ninth Circuit's decision, that function loses its significance. Rather than treating the materiality requirement as a means to facilitate the receipt of reliable information, the Ninth Circuit turns the requirement on its head and compels disclosure of purely anecdotal and random information involving a product. Simply put, that result cannot be squared with this Court's precedents.

2. Compelling public disclosure of anecdotal adverse event reports as "material" will hinder, not help, informed investment decisions.

Respondents here alleged that Matrixx and three of its executives violated § 10(b) and Rule 10b-5 by failing to disclose that the use of Zicam could cause "anosmia," or loss of the sense of smell. *See*

Appendix to the Petition ("App.") 3a. To support the supposed causal link between Zicam and anosmia, respondents alleged that over a four-year period, Matrixx received approximately 12 reports of user anosmia. App. 25a. Indisputably, however, respondents did not allege—because they could not—that the 12 adverse event reports were statistically significant. Nor did respondents allege—again, because they could not—that any one of these reports conclusively established an actual link between Zicam and anosmia or that any definitive medical or scientific study had revealed such a link during the class period.

The Ninth Circuit nonetheless reversed the district court's Rule 12(b)(6) dismissal, concluding that respondents had adequately pleaded materiality. In reaching that result, the court rejected the "statistical significance" standard for assessing the materiality of adverse event reports previously adopted by the First, Second and Third Circuits. The court found the standard to be inconsistent with this Court's supposed rejection of "bright-line" rules for determining materiality. App. 23a. Invoking this Court's reference in *Basic* to the "fact-specific inquiry" for assessing materiality, the court also concluded that materiality should be reserved for the trier of fact. *Id.*

The Ninth Circuit's holding compelling disclosure, without more, of a handful of adverse event reports severely undermines the materiality

requirement's filtering function in a number of ways. If that requirement is intended to compel disclosure of reliable information, then it should not be relied on to compel disclosure of a few anecdotal adverse event reports—particularly in the absence of any credible reasons for concluding that the pharmaceutical or medical device referenced in the reports actually caused the identified adverse event.

Indeed, far from showing such a causal link, the FDA's own regulations make clear that adverse event reports, on their own, show ***no*** causal relationship between a drug or device and the reported event. *See* 21 C.F.R. § 803.16; *see also In re Carter-Wallace, Inc. Securities Litig.*, 220 F.3d 36, 41 (2d Cir. 2000) (*Carter-Wallace II*) ("the receipt of an adverse report does not in and of itself show a causal relationship" between the drug or device and the events reported); S. Rep. No. 109-324, at 6 (2006) ("The fact of a report of an adverse event is not determinative that the event occurred or that the event was caused by a consumer's use of the product.").

The FDA makes this point even more explicitly on its website:

> [T]here is no certainty that the reported [adverse] event was actually due to the product. FDA does not require that a causal relationship between a product and

> event be proven, and reports do not always contain enough detail to properly evaluate an event. Further, FDA does not receive all adverse event reports that occur with a product. . . . Therefore, AERS cannot be used to calculate the incidence of an adverse event in the U.S. population.

U.S. Food and Drug Administration, Adverse Event Reporting System (last modified Aug. 20, 2009) *available at* http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/default.htm.

This kind of speculation has no role to play in a materiality determination. Rather, as noted, the materiality determination turns on whether the information that allegedly must be disclosed would be "substantial[ly] likel[y]" to influence a reasonable investor's decision whether to buy the company's stock. *Basic*, 485 U.S. at 231; *TSC*, 426 U.S. at 449. A disclosure showing nothing more than a hypothetical association between a company's product and a consumer's adverse reaction does not reach that threshold. Put another way, without additional evidence substantiating a possible causal link, no "reasonable investor" would expect the reported events to "'affect [the company's] future earnings.'" *Oran v. Stafford*, 226 F.3d 275, 284 (3d Cir. 2000) (Alito, J.) (quoting *In re Carter-Wallace*,

Inc. Securities Litig., 150 F.3d 153, 157 (2d Cir. 1998) (*Carter-Wallace I*)). That is so because "until a connection between [the drug] and any illness could be made, we would not expect [the manufacturer] to abandon its product on what, at the time, would have been speculation." *Carter-Wallace II*, 220 F.3d at 42.

Second, in this context, the unfiltered dissemination of anecdotal adverse event reports plainly would severely impair the "informed decisionmaking" this Court has endeavored to preserve. The sheer volume of information that would have to be disclosed would lead to the sort of information overload that this Court and commentators have recognized can paralyze a decisionmaker.[2] *See Basic*, 485 U.S. at 231-32; *TSC*, 425 U.S. at 448-49; *see also* Susanna Kim Ripken, *The Dangers and Drawbacks of the Disclosure*

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[2] In 2009, the FDA received a total of more than 580,000 adverse event reports for all drugs and "therapeutic biologic products," up from approximately 526,000 in 2008. *See* U.S. Food and Drug Administration, Adverse Event Reporting System (AERS), Reports Received and Reports Entered into AERS by Year (as of March 31, 2010), *available at* http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm070434.htm. The upward trend continued through the first quarter of 2010, when the FDA received nearly 160,000 reports for all drugs. *Id.* This comes as no surprise because "[f]ew if any drugs are completely safe in the sense that they may be taken by all persons in all circumstances without risk." *See United States v. Rutherford*, 442 U.S. 544, 555 (1979).

Antidote: Toward a More Substantive Approach to Securities Regulation, 58 BAYLOR L. REV. 139, 162 (2006) (noting that information "overload" in securities disclosures "can hinder informed decision-making and thereby defeat the very purpose of disclosure requirements"); Troy A. Paredes, *Blinded by the Light: Information Overload and its Consequences for Securities Regulation*, 81 WASH. U.L.Q. 417, 446 (2003) ("Meaningful, effective disclosure does not simply mean more disclosure. Because of information overload, in some cases, more disclosure can mean less effective disclosure."); Donald C. Langevoort, *Toward More Effective Risk Disclosure for Technology-Enhanced Investing*, 75 WASH. U.L.Q. 753, 759 (1997) ("[T]he more information there is, the more each bit of it is diluted. The immediate and salient crowds out the less attention-grabbing.").

Third, the greatest threat to "informed decisionmaking" posed by the Ninth Circuit's holding is the *quality*—or lack thereof—of the information it effectively requires pharmaceutical and medical device companies to convey. It should go without saying that "the higher the quality of information provided about available investment opportunities, the more often investors will put capital to its most productive and profitable uses." Sauer, *supra*, at 317. A handful of anecdotal adverse event reports fall well short of the qualitative standard that ought to govern what a public company must disclose to

the investing public. Until there is much greater substantiation of cause and effect, requiring disclosure of such speculative information promises only to confound investment decisions, not facilitate them.

As a result, it is hard to envision a more abrupt departure from this Court's precedents in *TSC* and *Basic* than the Ninth Circuit's holding that a few anecdotal adverse event reports are "material" and must be disclosed. Consistent with these decisions, the materiality requirement's most basic function is to limit what must be disclosed to reliable information that would influence a reasonable investor's decision. By parity of reasoning, under this Court's precedents, speculative information not only need not be disclosed, it should not be disclosed. The Ninth Circuit's decision, in contrast, sends an entirely different message: it threatens a manufacturer with liability for failing to disclose information that is, at its best, anecdotal and speculative. There is no colorable reason for the securities laws to operate in this fashion. This Court should reject the Ninth Circuit's holding and, in doing so, restore the materiality requirement's role in ensuring the flow of reliable information to the securities markets.

B. The Ninth Circuit's Materiality Analysis Undermines The Gatekeeping Function That Federal Courts Perform In Screening Potentially Abusive Securities Actions.

The Ninth Circuit compounds its failure to adhere to this Court's materiality precedents by all but ignoring this Court's controlling decisions for evaluating the sufficiency of a complaint's allegations: *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007) and *Ashcroft v. Iqbal*, 129 S.Ct. 1937 (2009). *See* App. 21a, 26a (citing *Twombly* twice and ignoring *Iqbal* entirely). Under the Ninth Circuit's approach, district courts within its jurisdiction will be unable to weed out securities lawsuits in circumstances where plausible allegations of materiality are not, and cannot, be made.

1. The Ninth Circuit's analysis effectively—and erroneously—immunizes materiality allegations from Rule 12(b)(6) challenges.

The Ninth Circuit applied a decidedly anti-*Twombly/Iqbal* rule to § 10(b)'s materiality requirement—that Rule 12(b)(6) challenges to the sufficiency of materiality allegations virtually can *never* succeed because materiality belongs solely in the province of the finder of fact. App. 22a ("[q]uestions of materiality . . . involv[e] assessments peculiarly within the province of the trier of fact")

(citations and quotations omitted); App. 23a ("courts should engage in a 'fact-specific inquiry' in assessing materiality [and] '[d]etermining materiality in securities fraud cases should ordinarily be left to the trier of fact'") (citations and quotations omitted). The Ninth Circuit's reasoning significantly diminishes any prospect of dismissing a § 10(b) claim at the pleadings stage based on deficient materiality allegations and, in that fashion, impermissibly conflicts with *Twombly* and *Iqbal*.

Twombly and *Iqbal* require district courts to assess whether a plaintiff's allegations "render [the plaintiff's claim to relief] plausible," that is, whether they contain "enough fact to raise a reasonable expectation that discovery will reveal evidence" of actionable conduct. *Twombly*, 550 U.S. at 556; *see also Iqbal*, 129 S.Ct. at 1949-51. Particularly pertinent to the materiality issues here, the Court has explained that "[d]etermining whether a complaint states a plausible claim for relief will . . . be a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Iqbal*, 129 S.Ct. at 1950 (citation omitted). And, there is no doubt that the "plausibility" analysis mandated by *Twombly* and *Iqbal* must be

applied to "all civil actions," including securities fraud claims. *See Iqbal*, 129 S.Ct. at 1953.[3]

Against this backdrop, the Ninth Circuit's exclusion of materiality allegations from the scrutiny envisioned in *Twombly* and *Iqbal* is not sustainable. Even before *Twombly* and *Iqbal*, courts had rejected the "broadly cast" assertion "that it is improper for a court deciding a Rule 12(b)(6) motion to dismiss a complaint on the basis of materiality" and concluded that "a court can determine statements to be immaterial as a matter of law on a motion to dismiss . . ." *See ABC Arbitrage Plaintiffs Grp. v. Tchuruk*, 291 F.3d 336, 359 (5th Cir. 2002) (Higginbotham, J.) (citations omitted).

The Fifth Circuit's pre-*Twombly* observations in *ABC Arbitrage* apply with equal force today and there is nothing unique about the materiality requirement that should spare it from a plausibility analysis *Twombly* and *Iqbal* demand. District courts can apply their recognized "judicial experience and common sense" to determine whether omitted information would have been substantially likely to influence a reasonable investor's decisionmaking, and this Court should encourage them to do so.

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[3] The need for plaintiffs to plead materiality consistent with *Twombly* and *Iqbal* is in addition to the statutory requirement that plaintiffs "specify the reason or reasons why" the alleged omission or misstatement of material fact is misleading. 15 U.S.C. § 78u-4(b)(1)(B).

Fidelity to *Twombly* and *Iqbal* in analyzing materiality allegations is especially vital given the abusive tendencies of securities fraud suits, the inordinate costs of defending them, and the secondary effects of these costs on the capital markets. *See Malack v. BDO Seidman LLP*, 2010 WL 3211088, at *10 (3d Cir. Aug. 16, 2010) ("Rule 10b-5 litigation, by its very nature, is costly. An increase in frivolous litigation drives up the overall costs of issuing securities, ultimately harming everyone involved.").

2. The Ninth Circuit's immunization of materiality allegations from Rule 12(b)(6) challenges facilitates the filing of abusive securities fraud strike suits.

The proliferation of such abusive "strike" suits and the threats they pose has been well-chronicled by this Court and Congress. This Court has recognized that "'litigation under Rule 10b-5 presents a danger of vexatiousness different in degree and in kind from that which accompanies litigation in general.'" *Merrill Lynch, Pierce, Fenner & Smith, Inc. v. Dabit*, 547 U.S. 71, 80 (2006) (citation omitted); *see also Stoneridge*, 552 U.S. at 163 (expressing concern "that extensive discovery and the potential for uncertainty and disruption in a lawsuit allow plaintiffs with weak claims to extort settlements from innocent companies"); *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 313

(2007) ("Private securities fraud actions, however, if not adequately contained, can be employed abusively to impose substantial costs on companies and individuals whose conduct conforms to the law.").[4]

Congress, too, has perceived the abusiveness in such suits and has legislated with the intent to curb it. Congress passed the Private Securities Litigation Reform Act of 1995 ("PSLRA") "[a]s a check against abusive litigation by private parties[.]" *Tellabs*, 551 U.S. at 313. The Committee Reports for the PSLRA are replete with findings of abusive securities fraud suits and their deleterious impact on public companies, their investors, and the capital markets. *See* S. Rep. No. 104-98, at 8-9 (1995) (finding that securities fraud suits "have added significantly to the cost of raising capital and represent a 'litigation tax' on business"); H.R. Rep. No. 104-369, at 31 (1995) (stating that Congress acted "to protect investors and maintain confidence in our capital markets" in response to "significant

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[4] The fact that § 10(b) claims typically are brought as class actions only magnifies these concerns with abuse and excessive costs. *See, e.g.*, *Gulf Oil Co. v. Bernard*, 452 U.S. 89, 99-100 (1981) (acknowledging that class actions "present . . . opportunities for abuse"); *Reiter v. Sonotone Corp.*, 442 U.S. 330, 345 (1979) (admonishing district courts to be "especially alert to identify frivolous [class] claims brought to extort nuisance settlements"); *Malack*, 2010 WL 3211088, at *11 (recognizing that class certification "'may . . . create unwarranted pressure to settle nonmeritorious claims on the part of defendants'") (citation omitted).

evidence" of abusive litigation tactics). Those Reports also reflect Congress's findings—equally if not more true today—that "[m]ost defendants in securities class action lawsuits choose to settle" and that such "cases are generally settled based not on the merits but on the size of the defendant's pocketbook." S. Rep. No. 104-98, at 8-9 (1995).

Beyond all this, the need for rigorous *Twombly/Iqbal* scrutiny of the plausibility of materiality allegations is particularly acute in "omission" securities fraud suits like respondents' here because plaintiffs in such actions generally do not need to plead the element of reliance. *See Stoneridge*, 552 U.S. at 159 (citing *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128, 154 (1972)). As a result, defendants in these kinds of cases are deprived of a key argument at the pleadings stage, thus amplifying the need to demand plausible materiality allegations in order to weed out abusive "omission" claims under § 10(b).

Nor will the adverse consequences that may follow from the Ninth Circuit's anti-*Twombly/Iqbal* rule be restricted to companies located or conduct that occurs within the Ninth Circuit's immense territorial jurisdiction—those consequences will impact pharmaceutical and medical device companies from coast-to-coast that sell their products throughout the fifty states, including the numerous states and territories in the Ninth Circuit. Moreover, the Securities Exchange Act provides for

nationwide service of process and personal jurisdiction in any United States forum based on sufficient contacts by a defendant anywhere in the United States. *See* § 27, 15 U.S.C. § 78aa; *Warfield v. Alaniz*, 569 F.3d 1015, 1029 (9th Cir. 2009). As a result, pharmaceutical and medical device companies face the very real threat of being haled into one of the more than dozen federal district courts in the Ninth Circuit to defend a § 10(b) claim based on undisclosed adverse event reports and being subjected to the decision below as a controlling precedent.

It is unlikely, moreover, that this expansion of liability will be confined to § 10(b) claims. Sections 11 and 12 of the 1933 Securities Act—which create private remedies for misstatements and omissions in registration statements and prospectuses—similarly require that the misstated or omitted fact meet a "materiality" standard. *See* 15 U.S.C. § 77k(a); 15 U.S.C. § 77*l*(a)(2). Thus, courts—including the Ninth Circuit—have concluded "that the standard of materiality is the same under section 10(b) as it is under section 11 . . ." *See, e.g., In re Worlds of Wonder Securities Litig.*, 35 F.3d 1407, 1424 (9th Cir. 1994). Courts in the Ninth Circuit faced with claims under these provisions therefore are likely to

follow the Circuit's decision below in determining the scope of "materiality."[5]

The Ninth Circuit's decision not only looses the materiality requirement from its moorings, but, by failing to bring the pleading analysis in *Twombly* and *Iqbal* to bear, undermines the district courts' recognized screening role as well. In combination, this erroneous analytical approach is certain to increase the number of securities lawsuits that survive the pleading stage, with the enhanced public and private costs that inevitably follow.

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[5] This prospect is all the more troubling because there is evidence of a recent upsurge in § 11 securities fraud claims as compared to § 10(b) suits. *See* David I. Michaels, *An Empirical Study of Securities Litigation After WorldCom*, 40 RUTGERS L. REV. 319, 336-43, 347 (2009). This trend is not surprising because unlike § 10(b), "[n]either [s]ection 11 nor [s]ection 12 (a)(2) requires that plaintiffs allege the scienter or reliance elements of a fraud cause of action." *Rombach v. Chang*, 355 F.3d 164, 169 n.4 (2d Cir. 2004).

C. The Ninth Circuit's Compelled Disclosure Of Adverse Event Reports Unnecessarily Threatens The FDA's Regulatory Role, Including Its Expert Oversight Of Pharmaceutical And Medical Device Labeling.

In the unique confines of a case involving pharmaceuticals or medical devices, particularly given the nature of the information that is being disclosed, declaring adverse event reports material engenders consequences that extend beyond the securities laws, securities litigation, and investors. While certainly not outcome determinative, these consequences at least should be considered where the question concerns—as it does here—the substantive legal standard that ought to be adopted under the securities laws.

Labeling information as "material" under the securities laws carries with it a regulatory directive that the information must be disclosed on penalty of civil or criminal liability. Further, in keeping with the statutory scheme, that disclosure must come from the company itself—in its own public filings with the appropriate regulatory agency.

To be sure, the public otherwise could find out about adverse event reports and those reports could make their way, as they did in this case, into the mainstream media. But in those instances, there is no regulatory compulsion or public company filing

behind the conveyance of the information.[6] And, while the public disclosures required here specifically are aimed at investors or shareholders, it would be naïve to think that their effect will end there. Rather, it is no leap of faith to conclude that the compelled disclosure of adverse event reports would impact the regulation and use of the pharmaceutical and medical devices they relate to.

For example, although not addressed or analyzed in the court's decision, the Ninth Circuit's compelled disclosure rule risks intruding on the FDA's oversight of pharmaceutical and medical device labeling. This intrusion profoundly threatens a critical part of the FDA's regulatory mission.

As this Court well knows, FDA approval of pharmaceuticals and medical devices is a "rigorous" process. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 317 (2008) (citation and internal quotations omitted). Manufacturers submit "new drug applications," which the FDA subjects to a "strict and demanding" review. *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 619, 627 (1973); *Riegel*, 552 U.S. at 318 (noting that the "FDA spends an average of

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[6] Indeed, where the securities laws are not involved, the company's First Amendment rights are not circumscribed by those laws and the disclosures they require—in such circumstances, the company can, as Matrixx did here, hold its own press conference or issue its own press release to defend its product and provide an unfettered explanation of why the purported risks should not be associated with its product.

1,200 hours reviewing each application" for premarket device approval). The FDA performs a "comprehensive scientific evaluation of the product's risks and benefits under the conditions of use prescribed, recommended, or suggested in the labeling." *FDA, Requirements on Content and Format of Labeling for Human Prescription Drugs and Biological Products*, 71 Fed. Reg. 3922, 3934 (Jan. 24, 2006). It "must 'weig[h] any probable benefit to health . . . against any probable risk of injury or illness" before approval—"[i]t may thus approve devices that present great risks if they nonetheless offer great benefits in light of available alternatives." *Riegel*, 552 U.S. at 318 (citation and quotations omitted).

A pivotal part of the FDA's review accordingly involves its examination of the drug's proposed labeling (*Riegel*, 552 U.S. at 318)—indeed, approval of an NDA must be based on an FDA finding that the pharmaceutical or medical device is safe and effective for use "under the conditions prescribed, recommended, or suggested in the proposed labeling thereof." 21 U.S.C. § 355(b)(1)(F), (d); *see also* 21 U.S.C. § 360c(a)(2)(B).

After approval, the manufacturer must investigate and report to the FDA any adverse events associated with the use of the product in humans, 21 C.F.R. § 314.80, and must periodically submit any new information that may affect the FDA's previous conclusions about safety,

effectiveness, or labeling, 21 C.F.R. § 314.81. The FDA, in turn, "monitors adverse events" from various reports and "uses this information to update drug labeling." *Postmarketing Surveillance Programs* (last modified Aug. 18, 2009) *available at* http://www.fda.gove/cder/regulatory/applications/Postmarketing/surveillancepost.htm. The FDA also "shall" withdraw its approval of an application if it finds, among other things, that the drug is not safe or effective under the conditions of use specified in the drug's labeling. *See* 21 U.S.C. § 355(e); 21 U.S.C. § 360e(e)(1); *Riegel*, 552 U.S. at 319-20.

Whether it relates to the original labeling on the pharmaceutical or device or any subsequent changes prompted by adverse event reports, the FDA's decisions as to what must be disclosed in a product's labeling are fact-based, science-based, and formulated with public health and safety in mind. The FDA's experts are compelled by regulation, and equipped by background, training and experience, to make these health and safety evaluations. The FDA does not require every adverse event or conceivable risk to be disclosed. To the contrary, it requires all labeling to be specifically supported by "reasonable evidence of a causal association" between the product and a particular side-effect. 21 C.F.R. § 201.57(c)(6)(i); *see also* 21 C.F.R. § 201.80(e) (requiring "reasonable evidence of an association of a serious hazard"). As a result, pharmaceutical and device labeling conveys only the information that in

the FDA's considered judgment is essential for the physician prescribing the product and the patient receiving it.

The Ninth Circuit, however, has compelled the disclosure—under the materiality requirement imposed by the securities laws—of adverse event reports without regard for pharmaceutical or device labeling or the FDA's independent evaluation. Plainly, as is true in this case, the Ninth Circuit's holding could compel the company to publicly disclose adverse event reports about a drug or device that the FDA has yet to deem substantial enough to require a change in labeling. In that instance, moreover, the manufacturer could not change its labeling on the one hand (by regulation; *see* 21 C.F.R. § 314.70(b)(2)(v)(A)), but would have to publicly disclose the purported risk in its own public filings on the other. This discrepancy threatens the credibility of the FDA's judgments about safety and effectiveness and disrupts the FDA's recognized roles in crafting and monitoring appropriate product labeling.

Here, the sort of "over-warning" of alleged risks that would follow from the compelled public disclosure increases the likelihood that the most important information about pharmaceuticals and medical devices—the labeling information specifically approved and mandated by the FDA—will be drowned out and overlooked. For instance, "excessive warnings can cause more meaningful risk

information to 'lose its significance.'" Br. *Amicus Curiae* U.S. at *17, *Wyeth v. Levine* (filed U.S. S. Ct. June 2, 2008), *available at* 2008 WL 2308908 ("*Wyeth* Br.") (quoting 44 Fed. Reg. p. 37,447 (1970); citing 71 Fed. Reg. p. 3935 (2006) and 65 Fed. Reg. p. 81,083 (2000)); *see also Robinson v. McNeil Consumer Healthcare*, 2010 WL 3156548, at *11 (7th Cir. Aug. 11, 2010) (Posner, J.) (acknowledging the likelihood of consumer "information overload" from prolix pharmaceutical warning labels); Center for Devices and Radiological Health, FDA, *Write it Right: Recommendations for Developing User Instruction Manuals for Medical Devices Used in Home Health Care* 7 (1993) ("Overwarning has the effect of not warning at all. The reader stops paying attention to excess warnings."). This is particularly true of "[w]arnings about dangers with less basis in science or fewer hazards"—*e.g.*, adverse event reports—which "could take attention away from those that present confirmed, higher risks." *Brooks v. Howmedica, Inc.*, 273 F.3d 785, 796 (8th Cir. 2001) (*en banc*).

In addition, such over-warning of alleged risks can motivate consumers to refuse to use a beneficial pharmaceutical or medical device based strictly on the untested and anecdotal information. *See Wyeth* Br., 2010 WL 2308908, at *17 (promoting the need to balance notice of "potential dangers" of drug "and not unnecessarily deterring beneficial uses through overwarning") (citing 71 Fed. Reg. p. 3395 (2006));

id. ("Exaggeration of risk could discourage appropriate use of a beneficial drug,' and thereby harm the public health.") (quoting 71 Fed. Reg. p. 3935 (2006)). This will generate even more costs to society. *See New Medicines Increase Productivity and Decrease Absenteeism*, PhRMA Two-Pager Plus, Winter 2004 (concluding that drugs could prevent nearly $30 billion dollars in lost work time due to treatable depression); *Value of Medicines*, PhRMA (discussing significant beneficial impact of pharmaceuticals) *available at* http://www.phrma.org/issues /value_of_medicines (last visited Aug. 20, 2010).

Even more problematic, however, is the way in which the compelled disclosures could invade the FDA's expert evaluations on what should be disclosed to the consuming public in the interests of public safety and health. As noted, prescription drug and device labeling is not intended to, and does not, disclose every purported risk that conceivably could be linked to a product. The principal reasons for this regulatory discipline are to help ensure that necessary warnings are heeded and that pharmaceuticals and devices will be utilized when they should be.

FDA regulation does not preempt the securities laws. But the securities laws are not intended to be a *sub rosa* public health disclosure statute either. Yet, that is exactly what those laws will become under the Ninth Circuit's holding, and

the conceptual problems that poses for the FDA's regulatory judgments should not be lightly dismissed in evaluating whether the Ninth Circuit's decision should become controlling law.[7]

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[7] There are other potentially troubling consequences that might follow from the adoption of the Ninth Circuit's reasoning. Under the Ninth Circuit's holding, manufacturers have no genuine choice on whether to disclose adverse event reports in their public securities filings—if they fail to do so, they will confront the almost-certain prospect of a securities fraud suit; if they do disclose, however, their public statements likely will prompt consumer lawsuits based on the discrepancies between the manufacturer's product labeling (as required by the FDA) and the "materiality" of the risks disclosed in its regulatory filings. In the end, therefore, one thing is clear: under the Ninth Circuit's decision, manufacturers face the prospect of escalating costs, with no good options for containing them. *See, e.g., Carlin v. Superior Court*, 920 P.2d 1347, 1361 (Cal. 1996) ("the imposition of excessive liability on prescription drug manufacturers may discourage the development and availability of life-sustaining and lifesaving drugs"); *Brown v. Superior Court*, 751 P.2d 470, 478 (Cal. 1988) ("the consuming public . . . will pay a higher price for the product to reflect the increased expense of insurance to the manufacturer resulting from its greater exposure to liability").

D. The "Statistical Significance" Standard For Disclosing Adverse Event Reports Effectuates The Materiality Requirement's Filtering Function, Furthers The Gatekeeping Function Federal Courts Perform In Screening Securities Lawsuits, And More Closely Comports With The FDA's Paramount Role In Regulating Pharmaceutical And Medical Device Labeling.

The "statistical significance" standard adopted by the First, Second and Third Circuits does not suffer from the same infirmities that plague the Ninth Circuit's decision. Instead, as applied in this case, that standard supports the filtering purpose of the materiality requirement, aligns with the plausibility inquiry required under *Twombly* and *Iqbal*, and comports much more closely with the FDA's recognized regulatory function.

The "statistical significance" standard first emerged in the Second Circuit's decision in *Carter-Wallace I*, 150 F.3d 153. Plaintiffs there asserted a § 10(b) claim based on Carter-Wallace's omission from its public securities filings that its anti-epileptic drug, Felbatol, was associated with patient deaths. The court rejected this claim, concluding that Carter-Wallace had no such duty to disclose under § 10(b) until it "had information that Felbatol had caused a statistically significant number of aplastic-anemia deaths and therefore had reason to

believe that the commercial viability of Felbatol was threatened." *Id.* at 157 (citation omitted). The court explained that "[d]rug companies need not disclose isolated reports of illnesses suffered by users of their drugs until those reports provide statistically significant evidence that the ill effects may be caused by-rather than randomly associated with-use of the drugs and are sufficiently serious and frequent to affect future earnings." *Id.* The Third Circuit and the First Circuit subsequently have endorsed *Carter-Wallace I* and adopted the statistical significance standard as well. *See Oran*, 226 F.3d at 284 (Alito, J.); *New Jersey Carpenters Pension & Annuity Funds v. Biogen IDEC Inc.*, 537 F.3d 35, 50 (1st Cir. 2008).

As far as the materiality requirement is concerned, the "statistical significance" standard supports, rather than undermines, the requirement's filtering function. Since it requires that adverse event reports be disclosed only when they collectively demonstrate something more than a mere chance of a causal link between the product and the adverse reaction—the point of "statistical significance"—the "statistical significance" standard spares investors and consumers from a barrage of unverified data about drugs and devices that would only impair the decisionmaking process.[8]

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[8] The "statistical significance" standard adopted by these circuits operatives effectively in cases like this one, where the undisclosed adverse event reports are statistically insignificant

Continued on following page

The "statistical significance" standard also squares with this Court's mandate that only "plausible" claims for relief should be permitted past the pleadings stage and through the gateway to discovery. *Iqbal*, 129 S.Ct. at 1949-50; *Twombly*, 550 U.S. at 555-56, 570. Specific and concrete allegations that undisclosed adverse event reports meet the statistical significance threshold provide a more plausible basis for concluding that a reasonable investor would have been influenced by those reports had they been disclosed. By comparison, given that an adverse event report, without more, reflects nothing more than a random association between the event and a pharmaceutical, something less than allegations of statistical significance in this context falls well short of substantiating the plausibility of a claim that a reasonable investor would have been influenced by that statistically insignificant report. *See In re Carter-Wallace II*, 220 F.3d at 42 (reasoning that "until a connection between [the pharmaceutical] and any illness could be made, we would not expect [the manufacturer] to abandon its

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Continued from previous page
in number, the association between drug and condition that the reports suggest has not been medically or scientifically substantiated at the time of the alleged non-disclosure, and there is no allegation that the company had reached an internal consensus that its drug's risks could affect the company's future earnings. *Compare In re Pfizer Inc. Securities Litig.*, 584 F. Supp. 2d 621, 633-36 (S.D.N.Y. 2008); *In re Bayer AG Securities Litig.*, 2004 WL 2190357, at *9-10 (S.D.N.Y. Sept. 30, 2004).

product on what, at the time, would have been speculation").

Finally, the "statistical significance" standard threatens far less havoc with the FDA's regulatory role than the Ninth Circuit's compelled disclosure of random adverse event reports. The FDA will not take corrective measures with respect to labeling or withdrawal of a pharmaceutical or medical device based on adverse event reports unless and until the amount of those reports provides "reasonable evidence of a causal association with a drug." 21 C.F.R. § 201.80(e). When the adverse event reports reach a level of statistical significance, therefore, it is much more likely that the FDA will have acted and potential conflicts will be minimized or avoided altogether.

On balance, it is apparent that the "statistical significance" standard responds to this Court's repeated emphasis that securities regulation is "'an area that demands certainty and predictability.'" *Central Bank of Denver, N.A. v. First Interstate Bank of Denver, N.A.*, 511 U.S. 164, 188 (1994) (quoting *Pinter*, 486 U.S. at 652). "[U]ncertainty" in § 10(b)'s "governing rules," the Court stressed in *Central Bank*, could lead some companies, "as a business judgment, to abandon substantial defenses and to pay settlements in order to avoid the expense and risk of going to trial." *Id.* at 189. A clear, objective rule requiring the disclosure of adverse event reports

only when they have reached a statistically significant number provides the requisite certainty.

CONCLUSION

For the reasons noted, *amicus* respectfully urges this Court to reverse the Ninth Circuit's judgment.

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AMICUS CURIAE BRIEF

No. 09-1156

IN THE

Supreme Court of the United States

MATRIXX INITIATIVES, INC., ET AL.,

Petitioners,

v.

JAMES SIRACUSANO AND NECA-IBEW PENSION FUND,

Respondents.

ON WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

BRIEF OF *AMICI CURIAE* MEDICAL RESEARCHERS DR. TONIA M. YOUNG-FADOK (MAYO CLINIC), DR. CURT D. FURBERG (WAKE FOREST), DR. ERIC J. TOPOL (SCRIPPS), AND DR. DAVID A. ETZIONI (MAYO CLINIC) IN SUPPORT OF RESPONDENTS URGING AFFIRMANCE

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BRIEF OF *AMICI CURIAE* MEDICAL RESEARCHERS DR. TONIA M. YOUNG-FADOK (MAYO CLINIC), DR. CURT D. FURBERG (WAKE FOREST), DR. ERIC J. TOPOL (SCRIPPS), AND DR. DAVID A. ETZIONI (MAYO CLINIC) IN SUPPORT OF RESPONDENTS URGING AFFIRMANCE

INTEREST OF *AMICI CURIAE*

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Amicus Curt D. Furberg, M.D., is Professor of Public Health Sciences and Senior Advisor to the Dean for Health Services Research and Health Policy

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[1] This brief has been filed with the written consent of the parties, which is on file with the Clerk of Court. Pursuant to Rule 37.6, *amici* affirm that no counsel for a party authored this brief in whole or in part, nor did any person or entity, other than *amici* or their counsel, make a monetary contribution to the preparation or submission of this brief.

at Wake Forest University School of Medicine. From 1979 to 1985, he was Chief of the Clinical Trials Branch of the National Heart, Lung, and Blood Institute of the National Institutes of Health (NIH) in Bethesda, Maryland. In 1986, he was appointed Director, Center for Prevention Research and Biometry, and Head, Section of Prevention Research and Biometry in the Department of Medicine at Wake Forest. From 1989 until 1999, he was Chairman of the Department of Public Health Sciences at Wake Forest. Under Dr. Furberg's leadership, the Center and the Department grew from one to approximately 300 persons. The Department successfully competes for NIH funding and in recent years has ranked nationally as one of the top two departments of its type for NIH funding. Dr. Furberg has more than three decades of expertise and experience in the areas of epidemiology and clinical trial design, conduct, monitoring, interpretation, and reporting. He is a national leader in the field. He has served as Principal Investigator or Scientific Project Officer on a large number of primarily cardiovascular clinical trials, having played a very active role in their design, conduct, monitoring, interpretation, and reporting. These trials documented the efficacy and safety of various interventions and led to improvements in the quality of care for millions of patients with coronary heart disease, heart failure, hypertension, or other vascular conditions. He has served or is currently serving on the Data Safety Monitoring Committees for over 50 clinical trials sponsored by the NIH, various foundations, the pharmaceutical industry, and others, including the Data Safety Monitoring Committees of two ongoing industry-sponsored trials. These committees monitor

the efficacy and safety of treatment and prevention trials in progress and are charged with recommending early trial termination, if efficacy is clearly documented or if harmful effects outweigh the benefits. Thus, Dr. Furberg is experienced in the generally accepted approaches to weighing favorable and unfavorable effects of interventions, primarily medications. He is frequently consulted on clinical trial issues by colleagues at academic institutions and has conducted trials sponsored by pharmaceutical companies. He consulted for Wyeth as an expert regarding the diet-drug combination fenfluramine-phenteramine (so-called "fen-phen") in determining the magnitude of the adverse effects associated with its use. He has also been an advisor to the World Health Organization (WHO) and is currently conducting a WHO-sponsored study in Sri Lanka as part of a program directed at non-communicable diseases in low- and middle-income countries.

Amicus Eric J. Topol, M.D., is the Director of the Scripps Translational Science Institute, a National Institutes of Health-funded program of the Clinical and Translational Science Award (CTSA) Consortium focused on advancing individualized medicine. He is the Chief Academic Officer of Scripps Health, a Senior Consultant cardiologist practitioner at Scripps Clinic, and Professor of Translational Genomics at The Scripps Research Institute. Prior to coming to Scripps, he served on the faculty of Case Western as a professor in genetics, chaired the Department of Cardiovascular Medicine at Cleveland Clinic for 15 years and raised its status to rank #1 by U.S. News and World Report for 11 consecutive years, and was Founder of the Cleveland Clinic Lerner College of

Medicine. His work in the genomics of heart attack has led to discovery of key genes recognized by the American Heart Association twice as top 10 research advances. As a leader in clinical trials of novel therapeutics, he administered recombinant t-PA to the first patient in 1984 and pioneered and led the clinical development of clopidogrel (Plavix), bivalirudin (Angiomax), and abciximab (ReoPro). He was the first physician to publish safety concerns on the cardiovascular risk of Vioxx. He has over 1,000 original peer-reviewed publications and has edited over 30 books, including the Textbook of Interventional Cardiology (5th ed.) and the Textbook of Cardiovascular Medicine (3rd ed.). He has been a medical innovator in wireless medicine, including wireless ECG telemetry, vital signs, remote monitoring for heart failure, and as a Founder and Vice-Chairman of the West Wireless Health Institute. Dr. Topol has been elected to the Institute of Medicine of the National Academy of Sciences and the American Association of Physicians, and has been recognized by the Institute of Scientific Information to be in the top 10 cited biomedical researchers in medicine in the past decade.

Amicus David A. Etzioni, M.D., MSHS, FACS, is Associate Professor of Surgery, Mayo Clinic College of Medicine, and Senior Associate Consultant, Division of Colon and Rectal Surgery, Mayo Clinic, Arizona. Dr. Etzioni has extensive expertise in health services research, the study of quality as it pertains to health care delivery. In his career as a health services researcher, he has published in a wide range of topics, including critical reviews of the status of medical evidence. His experience in analyzing and

synthesizing medical knowledge will be important in giving context to the discussions of the importance of different types of scientific evidence.

Amici's expertise is directly relevant to the question presented in this case. They are very familiar with different methods by which medical information is gathered, including case reports and case series. They are well acquainted with the means by which the strength of scientific evidence is assessed and the role of case reports in prompting scientific alerts and further investigation. They can therefore provide this Court with an important perspective regarding the type and quantum of evidence by which medical researchers and professionals routinely take action and make decisions.

SUMMARY OF ARGUMENT

Petitioners in this case contend that Adverse Event Reports (AERs) are not material information unless they reveal a statistically significant increased risk of harm from product use. Yet medical researchers and professionals do not follow such an approach. They do not ignore relevant medical data, including reports of adverse events, or wait until the information rises to the level of statistical significance. They do not restrict the data they consider to the results of randomized clinical trials. To the contrary – medical professionals frequently act on the basis of case reports and other information that may not meet the standard of statistical significance.

Randomized trials have important ethical, practical, and statistical limitations. Although side

effects are tolerated as part of efficacy studies, trials usually are not conducted merely to confirm the presence of serious side effects. Randomized trials are designed to evaluate desired outcomes, while monitoring for adverse outcomes. Thus, medical researchers would not perform a randomized controlled trial simply to examine whether the specific outcome of anosmia is linked to the intranasal gluconate gel used in Zicam products. It would be ethically unjustifiable to undertake a randomized trial solely to evaluate a complication such as anosmia.

Further, clinical trials generally lack the statistical "power" to detect rare side effects. The number of participants in randomized controlled trials is usually calculated to demonstrate statistical significance in terms of a chosen outcome, such as efficacy, and is not designed to reveal rare serious adverse effects.

Because of the limitations of randomized trials, the medical community also considers case reports and case series to be important sources of material information. Case reports and case series have played key roles in many decisions by the medical community to investigate apparent risks, modify procedures or guidelines, and take other kinds of action. Examples include the dangers of Thalidomide, the risks of oral contraceptives (particularly deep vein thrombosis and subsequent pulmonary embolus), the link between Reye's Syndrome and aspirin, the side effects of rofecoxib (Vioxx), the identification of Acquired Immunodeficiency Syndrome, commonly known as AIDS, and

complications arising from laparoscopic surgery for colon cancer.

With respect to pharmaceuticals, the Food and Drug Administration (FDA) has recognized that case reports and case series can play important roles in serving as "safety signals" and raising concerns about an excess of adverse events compared to what would be expected to be associated with a product's use. Notably, such reports need not rise to a statistically significant level in order to trigger action.

In fact, case studies have already formed a basis for action on the part of medical professionals with respect to the intranasal gluconate gel in Zicam products. Based on the information available in 2003, medical professionals had a reasonable basis for undertaking further investigation with respect to anosmia.

Statistical significance simply is not the "be-all" and "end-all" for the medical profession in identifying medical risks and formulating appropriate responses. Accordingly, statistical significance should not be used as a rigid, bright-line standard for defining the materiality requirement for reasonable investors in the context of medical risks.

The judgment should be affirmed.

ARGUMENT

A. There Are Ethical, Financial, and Scientific Limits on Randomized Trials.

Contemporary medical professionals practice evidence-based medicine, *i.e.*, "the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual

patients."[2] Medical professionals must integrate individual clinical expertise with the best available external clinical evidence from systematic research. In combining this range of data from various sources, medical professionals do not restrict their attention to information that meets a standard of statistical significance.

Rather, medical professionals rely on their personal experience, proficiency, and judgment developed through clinical practice. They also consult the best available external evidence, including clinically relevant research, both from basic sciences and from patient-centered clinical research into the efficacy and safety of therapeutic, rehabilitative, and preventive regimens. Good doctors must use both individual clinical expertise and the best available external evidence, because neither alone is sufficient.[3] Clinical expertise is necessary to determine if external evidence is applicable to or appropriate for an individual patient. Consulting current best evidence is necessary to prevent practice becoming out of date.

Ever since the concept of randomization was first introduced by Fisher in agricultural research in 1926, randomized clinical trials (prospective studies comparing the effect and value of interventions against a control) or meta-analyses (the systematic reviews of several randomized trials) have often been treated as the "gold standard" for judging whether a

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[2] Sackett DL, Rosenberg WMC, Muir Gray JA, Haynes RB, Richardson WS. Evidence based medicine: What it is and what it isn't. Brit Med J (1996) 312:71-72.

[3] *Id.*

treatment does more harm than good.[4] In a randomized trial, a participant is randomly assigned to either the "study" group (which receives the particular intervention at issue) or the "control" group (which does not receive the intervention). The ideal trial is one that is randomized and double-blinded – neither the participant nor the investigator knows if the participant is in the study group or the control group.

However, evidence-based medicine is not restricted to the results of randomized trials or meta-analyses. Indeed, the practical reality is that many questions about medical care and treatment do not require randomized trials or cannot wait for trials to be conceived and conducted. And if there is no evidence from a randomized trial that addresses a patient's situation, it is important to look for the next best external evidence. As a leading pharmaceutical manufacturer explains on its website, "[r]esults from clinical studies, spontaneous reports, epidemiology studies, and, where relevant, preclinical datasets, should all be evaluated for their potential to address the particular safety question raised, taking into account the unique strengths and limitations of the study designs and data collection methods used."[5]

In some situations, randomized trials are precluded on ethical grounds – for example, where researchers have a reasonable basis for believing that members of the study group or control group will

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[4] Friedman LM, Furberg CD, DeMets DL. "Fundamentals of Clinical Trials" (4th ed. 2010, Springer-Verlag, New York), p. 1.

[5] http://media.pfizer.com/files/health/medicine_safety/2-5_How_is_Epidemiology_Used.pdf (last accessed November 4, 2010).

experience serious harm.[6] To be sure, there never has been, and never will be, a randomized trial of the benefits of parachutes for skydivers. Similarly, researchers typically do not conduct randomized trials if they already have a basis for believing that a particular intervention would have serious negative side effects that outweigh any potential positive gain from the intervention.

Moreover, clinical trials generally are not undertaken merely to confirm the existence of already suspected serious side effects. To be sure, physicians often observe a side effect when investigating an intervention's efficacy in treating a disease, but it is an entirely different matter to expose study subjects to serious side effect risks simply to confirm that those risks exist. Medical ethics would severely limit the types of investigations that would be permissible in such circumstances.

In this case, there would be serious ethical questions about a clinical trial of the intranasal gluconate gel used in Zicam products, given what doctors already know about the serious side effect risk of anosmia. Because of the obvious ethical concerns, researchers would be highly unlikely to

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[6] AMA Code of Medical Ethics, Opinion 2.07, subpart (2) ("In conducting clinical investigation, the investigator should demonstrate the same concern and caution for the welfare, safety, and comfort of the person involved as is required of a physician who is furnishing medical care to a patient independent of any clinical investigation."); *id.* at subpart (5)(a) ("Adequate safeguards must be provided for the welfare, safety, and comfort of the subject. It is fundamental social policy that the advancement of scientific knowledge must always be secondary to primary concern for the individual.").

conduct a randomized study merely to make sure that subjects really will lose their sense of smell.

Further, randomized trials typically lack the "power" to detect adverse effects that occur only rarely. In statistical terms, the ability of a study to detect a "real" effect is often referred to as the "power" of a study, or the probability that the study will lead to the identification of a true effect, as opposed to being the result of chance.[7] Statistical power is a function of the size of the treatment effect, the number of study participants, and the duration of the study. Trials are generally designed to examine a single goal, such as efficacy, or a very limited number of endpoints that are clearly stated in advance. Efficacy studies, which test an endpoint occurring with high frequency in smaller sample sizes, are simply not powered to detect rare adverse events. Hence, unless the control and study groups are very large and are followed for a substantial period of time (both of which greatly increase the cost of the investigation), the trial is unlikely to identify adverse effects that occur relatively rarely in the population.

In the case of the intranasal gluconate gel used in Zicam products, several randomized trials actually have been performed. Two randomized trials have reported that intranasal zinc is ineffective in preventing or reducing the duration of the common cold.[8] In the study by Belongia et al., 81 patients

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[7] Piantadosi, S. Clinical Trials: A Methodologic Perspective (1997), p. 528.

[8] Belongia EA, Berg R, Liu K. A randomized trial of zinc nasal spray for the treatment of upper respiratory illness in adults. Am J Med (2001) 111(2):103-08; Turner RB.

were randomized to receive zinc gel and 79 to placebo. Review of adverse events did not include a report of anosmia, but the study would have been underpowered to demonstrate such a rare side effect. A study by Hirt et al. did show a shorter duration of cold symptoms, and did not report anosmia, but only 108 and 105 patients were assigned to the study and control groups, respectively.[9] And a study by Mossad involved only 78 patients total, with 40 in the study group and 38 in the placebo.[10] In other words, none of the trials could have been expected to detect anosmia as a side effect.

Moreover, to the extent that an adverse event occurs in a clinical trial designed to assess the efficacy of treatment, it is unlikely that there would be a sufficient number of adverse events to achieve statistical significance at the 95% confidence level. However, lack of statistical significance should not be mistaken either for an absence of increased risk of harm or for confirmation that a drug is safe. As one researcher noted in the context of Bextra (valdecoxib), a non-steroidal anti-inflammatory drug (NSAID) removed from the market in 2005, due to

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Ineffectiveness of intranasal zinc gluconate for prevention of experimental rhinovirus colds. Clin Infectious Dis (2001) 33(11):1865-70.

[9] Hirt M, Nobel S, Barron E. Zinc nasal gel for the treatment of common cold symptoms: a double-blind, placebo-controlled trial. Ear, Nose & Throat J (2000) 79(10):778-80, 782.

[10] Mossad, SB. Effect of zincum gluconicum nasal gel on the common cold in otherwise healthy adults. QJ Med (2003) 96:35-43.

concerns about possible increased risk of heart attack and stroke:

> The . . . argument that the event rate for cardiovascular thrombotic events is not statistically significant different from placebo is technically correct but misses the point that statistical significance is not an appropriate threshold for the evaluation of clinical safety data: theoretically, one event may be of clinical significance.[11]

The Institute of Medicine of the National Academies reports that pre-market trials generally involve no more than 600 to 3,000 patients and that such trials cannot reveal the safety problems that may emerge only after long-term, large-scale use:

> Preapproval trials typically are too small to detect even significant safety problems if they are rare. An adverse event (even a serious one) that occurs in less than one in 1,000 patients cannot be reliably detected except in the largest premarket trials but can pose a serious public health problem when hundreds of thousands or millions of people use the drug.[12]

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[11] Lyons, et al. Valdecoxib Second Article 31 Procedure Rapporteur's and Co-rapporteur's Joint Assessment Report (2005 Jan 26).

[12] Institute of Medicine. The Future of Drug Safety: Promoting and Protecting the Health of the Public (Alina Baciu, Kathleen Stratton & Shelia P. Burke eds., 2007), pp. 37-38 (citations omitted).

As one major drug company – Pfizer – acknowledges on its website, "preapproval studies are rarely large enough to detect small differences in the risk of common adverse events or to reliably estimate the risk of rare events."[13]

A well-publicized contemporary example of the limited power of pre-approval studies is Vioxx, which has now been withdrawn over safety concerns. Rofecoxib was approved by the FDA on May 20, 1999, and was marketed by Merck & Co. under the brand name Vioxx. Indications for prescription were treatment of osteoarthritis, acute pain conditions, and dysmenorrhoea. Rofecoxib was widely prescribed by physicians treating patients with arthritis and other conditions causing chronic or acute pain. Worldwide, it is estimated that over 80 million people were prescribed rofecoxib prior to its 2004 withdrawal, over concerns about increased risk of vascular disorders such as heart attack and stroke associated with long-term, high-dosage use.[14]

The decision to withdraw the drug from the market was based on data from a study of rofecoxib in the prevention of colonic polyps (adenomas) (APPROVe) trial. In this study 2,586 patients were randomized to rofecoxib (25 mg/day) or placebo with a planned follow-up of three years.[15] Tellingly, the

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[13] http://media.pfizer.com/files/health/medicine_safety/2-5_How_is_Epidemiology_Used.pdf (last accessed November 4, 2010).

[14] Merck News Release dated September 30, 2004, *available at* http://www.merck.com/newsroom/vioxx/pdf/vioxx_press_release_final.pdf (last accessed November 4, 2010).

[15] Bresalier RS, Sandler RS, Quan H, Bolognese JA, Oxenius B, Horgan K, Lines C, Riddell R, Morton D, Lanas A, Konstam

decision to withdraw the medication from the market (September 30, 2004) was made prior to publication of the article in the New England Journal of Medicine (NEJM) (March 17, 2005) and reflects the behind-the-scenes reporting of results by Merck to the FDA and the NEJM. Safety monitoring of adverse events indicated a significant excess difference in the incidence of thrombotic cardiovascular events (such as myocardial infarction and stroke) in the study group that received rofecoxib. Other studies reported similar risks.[16]

These studies are illustrative of the difficulty in eliciting the risk of rare but serious outcomes during randomized controlled trials. Randomized trials are "powered" to show statistically significant common outcomes, not rare complications. Relatively rare side effects may not be noted and reported until the medication becomes available to a much larger population of patients. The Vioxx example involved an extremely well-funded trial of nearly 2,600 patients, and even then there was controversy regarding whether the risk of cardiac events was realized at the time of the first data analysis.

For all these reasons, statistically significant evidence from randomized trials is not the sole source of material information for medical professionals.

MA, Baron JA. Cardiovascular events associated with rofecoxib in a colorectal adenoma chemoprevention trial. N Engl J Med (2005) 352(11):1092-102. Epub 2005 Feb 15.

[16] Kerr DJ, Dunn JA, Langman MJ, Smith JL, Midgley RS, Stanley A, Stokes JC, Julier P, Iveson C, Duvvuri R, McConkey CC. Rofecoxib and cardiovascular adverse events in adjuvant treatment of colorectal cancer. N Engl J Med (2007) 357(4):360-69.

Nor is statistical significance equivalent to the legal burden of proof.[17]

B. Case Reports and Case Series Represent Important Sources of Information for Medicine and Epidemiology.

In view of the limits of randomized trials, medical researchers and professionals rely on other methods of determining the value, or harm, of interventions. These methods fall within the broader field of epidemiology, which can be defined as the study of the distribution and determinants of disease frequency in human populations. Epidemiology is based on the fundamental assumptions that human disease does not occur at random and that human disease has causal and preventive factors that can be identified through systematic investigation.[18]

Epidemiological principles and methods are concerned with *frequency*, *distribution*, and *determinants* of disease. Measuring disease *frequency* involves quantifying disease occurrence. Determining the *distribution* of disease involves investigating who is getting the disease within a population and perhaps where and when. These factors are important in describing patterns of disease and formulating a hypothesis regarding possible causal or preventive factors. The third component of epidemiology, the *determinants* of disease, is related to the first two, because data

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[17] Green, MD, Freedman, DM, Gordis, L. Reference Guide on Epidemiology (2000, Federal Judicial Center), p. 358 n.67.

[18] Hennekens CH, Buring JE. In Epidemiology in Medicine (1987, Little, Brown and Company, Boston/Toronto), p. 3.

regarding frequency and distribution of disease are required to test an epidemiologic hypothesis.

Epidemiological researchers use many types of studies. The basic design strategies can be broadly categorized into two types, depending on whether the study describes the distributions of disease or analyzes its determinants.[19] Descriptive epidemiology investigates the distribution of disease, including, for example, the populations or subgroups that do (or do not) develop a particular disease or symptom. Analytic epidemiology looks at the determinants of disease by testing hypotheses formulated from descriptive studies.

Descriptive studies are thus important in bringing to light new ideas regarding potential cause-and-effect associations and formulating hypotheses for further evaluation. Descriptive studies include correlational studies, case reports and case series, and cross-sectional surveys.

A correlational study uses data from large populations to compare the frequency of a specific disease between different populations during the same time period or the same population during different time periods.[20] For example, researchers have found that the risk of developing colon cancer is associated with various dietary components. When scientists compare the national per capita consumption of meat with rates of colon cancer in women from multiple countries, they find a positive correlation between per capita national meat

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[19] *Id.*

[20] *Id.*

consumption and development of colon cancer. This approach, however, offers only the view from 100,000 feet. Because correlational studies focus on large populations, it is impossible to determine if the women who develop colon cancer in each country are those with the highest intake of meat. The only conclusion that can be drawn is that populations with the highest intake have the highest rate of colon cancer. Meat may not be the causative factor, but instead a "marker" for other potentially causative traits, such as grilled food, obesity, high caloric intake, low fiber intake, lack of exercise, and so on. Such correlational data can raise hypotheses that require further analytic testing.

The case report is the most basic type of descriptive study and involves a detailed report by one or more experienced clinicians of a case considered rare and thus worthy of attention. These reports provide details of patients presenting symptoms and signs that have not previously been reported, or only rarely reported, in the medical academic literature. Case reports play key roles in medical treatment. When physicians encounter a case or constellation of symptoms and findings they have not seen before, nor even heard described, they look to case reports and small case series for information about how to manage such unusual conditions. These are the types of cases that are not addressed by textbooks or conventional medical training. They are simply too rare.

Case series are equally important to medical professionals. A case series alerts the medical community that a physician, or team of collaborating physicians, has identified a constellation of symptoms

or signs, not previously reported, in more than one patient. Case reports and case series are reported to a larger audience in various ways, including local presentation to an institutional division or department meeting that confirms the rarity of the condition, or formal presentation at a regional or national medical society meeting in the form of a poster, video, or podium presentation, that may garner attention or inspire further investigation, or publication in a medical journal.

Medical professionals do not limit their focus to statistically significant data in published studies. Indeed, they do not limit their concern to published data at all. Many notable case reports and case series are never published in medical journals, often due to the pressures that affect publication, even though many journals have acknowledged that case reports are the most widely read pieces among their audience. However, medical journals have a strong incentive to carry articles that will in turn be cited by other peer-reviewed articles, because the number of such citations forms the basis of a journal's significance (or impact factor). Thus, a medical journal has an interest in carrying articles that describe common conditions, because such articles are more likely to be cited elsewhere and thereby increase the journal's impact factors. Case reports, even though they are the favorites of the readership, have little impact factor, because they tend to be rarely cited in light of the fact that, by definition, the conditions they describe are rare. Some journals have even excluded case reports and case series altogether. Such exclusion does not diminish their ability to effect investigation and change, but it does

mean that focusing on published medical literature can create a false impression of the kind of information that forms a basis for action by medical researchers and professionals.

Medical journals and medical societies that publish reviews and guidelines will frequently ascribe "levels of evidence" to conclusions and recommendations. There is no single grading system. One system has been developed by the American Thoracic Society, which convened the Grades of Recommendation, Assessment, Development, and Evaluation (GRADE) working group to conduct a review of existing grading systems and develop a system for grading the quality of evidence and strength of recommendations of clinical practice guidelines (CPG).[21] Other societies have adapted this system, including the American Society of Colon and Rectal Surgeons. Yet other groups, such as the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES), use a more simplified approach.[22]

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[21] Schunemann HJ, Jaeschke R, Cook DJ, Bria WF, El-Solh AA, Ernst A, Fahy BF, Gould MK, Horan KL, Krishnan JA, Manthous CA, Maurer JR, McNicholas WT, Oxman AD, Rubenfeld G, Turino GM, Guyatt G. ATS Documents Development and Implementation Committee. An official ATS statement: grading the quality of evidence and strength of recommendations in ATS guidelines and recommendations. Am J Respiratory & Critical Care Med (2006) 174(5):605, 612.

[22] Wexner SD, et al. A Consensus document on bowel preparation before colonoscopy: prepared by a task force from the American Society of Colon and Rectal Surgeons (ASCRS), the American Society for Gastrointestinal Endoscopy (ASGE), and the Society of American Gastrointestinal Surgeons (SAGES). Dis Colon & Rectum (2006) 49:792-809; Perry WP, et

All of these scoring systems recognize an important role for observational studies, case reports, and case series, particularly where no randomized controlled trials are available.

C. Case Reports or Case Series Have Formed the Basis for Action in Many Well-Known Instances.

The FDA has recognized that case reports and case series can play important roles in serving as "safety signals" and raising concerns about an excess of adverse events compared to what would be expected to be associated with a given product's use.[23] Such reports need not rise to a statistically significant level in order to trigger FDA action. In fact, the FDA states that "[i]t is possible that even a single well-documented case report can be viewed as a signal, particularly if the report describes a positive rechallenge or if the event is extremely rare in the absence of drug use."[24] Pfizer similarly observes that "a safety signal [is] reported information on a possible causal relationship between an adverse event and a drug, the relationship being unknown or incompletely documented previously. When a safety signal is identified, further investigation is generally

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al. Practice parameters for the management of anal fissures (3rd revision). Dis Colon & Rectum (2010) 53:1110-15.

[23] U.S. Department of Health and Human Services, Food and Drug Administration. Guidance for Industry: Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment (2005 Mar), p. 4, *available at* http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126834.pdf.

[24] *Id.*

warranted to determine whether an actual connection exists."[25] FDA regulations do not require a statistically significant association between a drug and a given effect to warrant a label change such as a precaution or warning. *See* 21 C.F.R. § 201.57(e) ("The labeling shall be revised to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug; a causal relationship need not have been proved.").

Accordingly, case reports and case series have often spurred the medical community to investigate apparent risks, modify procedures or guidelines, and take other kinds of action. For example, the dangers of the drug Thalidomide when administered during pregnancy originally came to light through the publication of a letter in The Lancet, in December 1961, by an Australian gynecologist and obstetrician, noting a large number of birth defects in children of patients who had been prescribed the drug.[26] Thus, a case report was the initial trigger of the public response to the Thalidomide tragedy, which led to substantial regulatory reforms in the United States and elsewhere.

In addition, risks of oral contraceptives were initially identified through case reports.[27] Physicians now accept that the use of oral contraceptives is associated with an increased risk of deep vein

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[25] http://media.pfizer.com/files/health/medicine_safety/2-4_What_is_a_Safety_Signal.pdf (last accessed November 4, 2010).

[26] William McBride, Letter to the Editor, in The Lancet, 16 Dec 1961.

[27] Hennekens CH, Buring JE. In Epidemiology in Medicine (1987, Little, Brown and Company, Boston/Toronto), p. 3.

thrombosis (DVT), in which clots form in the deep veins of the legs, and subsequent pulmonary embolus (PE), in which a portion of the clot in the leg detaches and travels back to the lung in the venous system, causing chest pain, shortness of breath, and death, if it blocks the venous return of blood to the heart. Investigation of this phenomenon began in 1961 with a case report of a 40-year-old premenopausal woman who presented with a PE five weeks after starting an oral contraceptive for endometriosis. Because PE was more common in post-menopausal women, the author of the case report hypothesized that the medication may have been instrumental in the development of the clot. Subsequent studies, stimulated by this report, have consistently shown correlation between use of oral contraceptives and risk of DVT and PE. Currently, the manufacturer-informational-insert in every pack of oral contraceptives includes a warning regarding the risk of DVT and PE, and additionally advises against the use of this medication in women who smoke, as further study has indicated this is an additional risk factor for DVT and PE.

Another complication that was identified through initial case reports is Reye's Syndrome, an encephalopathy that develops during the course of varicella (chicken pox) infection in children and typically presents with a distinct constellation of symptoms including nausea, vomiting, headache, excitability, delirium, and combativeness with frequent progression to coma. It can also involve

liver dysfunction or failure.[28] The mortality rate of Reye's Syndrome can approach 30%. The syndrome was first described in Australia in 1963, and that same year the Centers for Disease Control (CDC) initiated a registry of cases in the United States.[29] By 1982, over 2,000 cases had been reported.

Case reports and case series played a significant role in the investigation of Reye's Syndrome. As sporadic reports accumulated, they raised suspicion of a link with the use of salicylate (aspirin). This prompted a number of case-control studies in the United States between 1978 and 1989, showing an association between Reye's Syndrome and aspirin.[30]

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[28] Hurwitz ES, Nelson DB, Davis C, Morens D, Schonberger LB. National surveillance for Reye syndrome: a five-year review. Pediatrics (1982 Dec) 70(6):895-900.

[29] Porter JD, Robinson PH, Glasgow JF, Banks JH, Hall SM. Trends in the incidence of Reye's syndrome and the use of aspirin. Arch Dis Child (1990) 65:826-29.

[30] Starko KM, Ray CG, Dominguez LB, Stromberg WL, Woodall DF. Reye's syndrome and salicylate use. Pediatrics (1980) 66:859-64; Hallpin TJ, Holtzhauer FJ, Campbell RJ, et al. Reye's syndrome and medication use. JAMA (1982) 248:687-91; Waldman RJ, Hall WN, McGee H, VanAmburg G. Aspirin as a risk factor in Reye's syndrome. JAMA (1982) 247:3089-94; Hurwitz ES, Barrett MJ, Bregman D, et al. Public Health Service study on Reye's syndrome and medications: report of the pilot phase. N Engl J Med (1985) 313:849-57; Hurwitz ES, Barrett MJ, Bregman D, et al. Public Health Service Study of Reye's syndrome and medications: report of the main study. JAMA (1987) 257:1905-11; Forsyth BW, Horwitz RI, Acampora D, et al. New epidemiologic evidence confirming that bias does not explain the aspirin/Reye's syndrome association. JAMA (1989) 17:2517-24; Belay ED, Bresee JS, Holman RC, Khan AS, Shahriari A, Schonberger LB. Reye's syndrome in the United

Consequently, public health authorities required warning labels to be placed on aspirin products and introduced a public education campaign throughout the United States in 1985, advising against the administration of aspirin to febrile children. Since aspirin use was identified as a major precipitating factor for the development of Reye's Syndrome,[31] this complication has virtually disappeared. In a surveillance study from 1980 through 1997, 1,207 cases were reported; the number of cases peaked in 1980 at 555 and dramatically declined thereafter, after warnings were issued against the use of aspirin in patients with varicella or influenza.[32] From 1987 to 1993, fewer than 36 cases per year were reported; fewer than two cases per year were noted from 1994 to 1997. Currently, Micromedex lists the following as a contraindication to the use of aspirin: "children and teenagers with chickenpox or flu symptoms (risk of Reye's syndrome)." This major change in prescribing practice arose because of the astute reporting of a previously unexpected link between the medication and a severe adverse effect.

One of the most famous medical discoveries to have emerged through case series is Acquired Immunodeficiency Syndrome, commonly known as AIDS. In 1981, for example, the CDC assimilated the

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States from 1981 through 1997. N Engl J Med (1999) 340(18):1377-82.

[31] Hurwitz ES, Barrett MJ, Bregman D, et al. Public Health Service study on Reye's syndrome and medications: report of the pilot phase. N Engl J Med (1985) 313:849-57.

[32] Belay ED, Bresee JS, Holman RC, Khan AS, Shahriari A, Schonberger LB. Reye's syndrome in the United States from 1981 through 1997. N Engl J Med (1999) 340(18):1377-82.

reports of several investigators who reported the diagnosis of *Pneumocystis carinii* pneumonia in five patients at three Los Angeles hospitals in a 6-month period from 1980 to 1981.[33] This was a rare causative organism for pneumonia, previously seen only in immunocompromised, older men and women, such as transplant patients. The common factor was that the five patients were all previously healthy homosexual men. Given the characteristics of the otherwise healthy group, further investigation proceeded and confirmed the diagnosis of this newly described disease. In the absence of the reported case series, the confirmation of the AIDS diagnosis could not have been made in a timely fashion.

Another recent example reveals the importance of case reports and case series in changing clinical practice.[34] The current era of laparoscopic or minimally invasive surgery commenced with the introduction of laparoscopic cholecystectomy (removal of the gallbladder) in 1987 in France[35] and in 1988 in the United States by Reddick and Olsen.[36] This procedure was rapidly accepted by patients and surgeons alike, and this led to the application of minimally invasive techniques to other operations.

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[33] Centers for Disease Control. Pneumocystis pneumonia – Los Angeles. MMWR (1981) 30:250.

[34] Young-Fadok TM. Minimally invasive techniques for colorectal cancer. Surg Oncol (1998) 7(3-4):165-73.

[35] Dubois F, Icard P, Berthelot G, Levard H. Coelioscopic cholecystectomy: Preliminary report of 36 cases. Ann Surg (1990) 211:60-62.

[36] Reddick EJ, Olsen DO. Laparoscopic laser cholecystectomy: A comparison with mini-lap cholecystectomy. Surg Endosc (1989) 3:131-33.

The first report of laparoscopic colon resection was by Jacobs et al. in 1991.[37] In 1993, within two years of the introduction of laparoscopic colon resection, the first sporadic cases of port-site metastasis (cancer recurrence at the laparoscopic incision sites) were reported.[38] Alexander et al. were the first to report on a 67-year-old man diagnosed with port-site metastasis after laparoscopic-assisted right colectomy for Dukes' C colon cancer.[39] This was followed by a report from O'Rourke et al., who described an 82-year-old woman with two port-site metastases, after resection for a Dukes' B adenocarcinoma.[40] Berends et al. reported a particularly alarming example of three tumor recurrences in only 14 patients.[41] These reports raised a great deal of concern, particularly in comparison with the low risk of wound recurrence in open colectomy for cancer.[42] In the next two years, at

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[37] Jacobs M, Verdeja JC, Goldstein, HS. Minimally invasive colon resection (laparoscopic colectomy). Surg Laparosc Endosc (1991) 1:144-50.

[38] Zmora O, Wexner SD. Part I: Laparoscopic surgery for colon and rectal cancer. Current Problems in Cancer (2001) 25(5):286-309.

[39] Alexander RJ, Jaques BC, Mitchell KG. Laparoscopically assisted colectomy and wound recurrence [letter]. Lancet (1993) 341:249-50.

[40] O'Rourke N, Price PM, Kelly S, Sikora K. Tumor inoculation during laparoscopy [letter]. Lancet (1993) 342:368.

[41] Berends FJ, Kazemier G, Bonjer HJ, Lange JF. Subcutaneous metastases after laparoscopic colectomy [letter]. Lancet (1994) 334:58.

[42] Reilly WT, Nelson H, Schroeder G, Wieand HS, Bolton J, O'Connell MJ. Wound recurrence following conventional treatment of colorectal cancer: A rare but perhaps

least 35 cases of port-site recurrence were reported in the literature by Johnstone et al.,[43] raising the possibility that there was some unknown aspect of the laparoscopic approach that might actually compromise cure.

At the same time, a group of practiced colorectal surgeons with initial experience with the laparoscopic approach had been developing plans for a randomized controlled trial to evaluate cancer outcomes and potential benefits of the laparoscopic approach (Clinical Outcomes of Surgical Therapy (COST) Study Group). The issue of wound implants led the group of surgeons to review their own cases[44] to determine if the same wound issues had arisen in their practices. They analyzed their own results from 372 laparoscopic procedures performed for colorectal cancer from 1991 through 1995. With a mean follow-up of 22.6 months, Kaplan-Meier survival curves by tumor TNM stage were similar to those reported for open colectomy by the National Cancer Institute Surveillance, Epidemiology, and End Results (SEER) Program. There were four wound implants, for an overall incidence of 1.08%, or an incidence of 4 of 304 (1.3%) potentially curable patients. With this

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underestimated problem. Dis Colon & Rectum (1996) 39(2):200-07.

[43] Johnstone PA, Rohde DC, Swartz SE, Fetter JE, Wexner SD. Port site recurrences after laparoscopic and thoracoscopic procedures in malignancy. J Clin Oncol (1996) 14(6):1950-56.

[44] Fleshman JW, Nelson H, Peters WR, Kim HC, Larach S, Boorse RR, et al. Early results of laparoscopic surgery for colorectal cancer: retrospective analysis of 372 patients treated by Clinical Outcomes of Surgical Therapy (COST) study group. Dis Colon & Rectum (1996) 39(suppl):53S-58S.

reassurance from their own experience that the laparoscopic approach did not entail higher incidences of wounds or tumor recurrences, the COST group proceeded with its randomized controlled trial.

Before the trial was concluded, however, there was a significant policy change. Both the American Society of Colon and Rectal Surgeons (ASCRS) and the Society of American Endoscopic and Gastrointestinal Surgeons (SAGES) published policy statements in their respective journals, recommending that laparoscopic colectomy for curative intent should be performed only under the auspices of a randomized controlled trial or in the setting of careful prospective follow-up of outcomes.[45]

Results of the landmark U.S. randomized COST trial were published in the spring of 2004 and showed equivalent cancer outcomes in the open and laparoscopic groups of the study. The data suggested that the laparoscopic procedure was safe in experienced hands.[46] In the meantime, few laparoscopic colon resections for colon cancer had been performed in the general population, a result of the ASCRS and SAGES policy statements. A subsequent policy statement, after publication of the results of the randomized COST trial, noted that the trial had shown equivalent results "in experienced hands" and recommended that laparoscopic resection

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[45] American Society of Colon and Rectal Surgeons. Approved statement: laparoscopic colectomy. Dis Colon & Rectum (1994) 37:638.

[46] Nelson H, Clinical Outcomes of Surgical Therapy Study Group. A comparison of laparoscopically assisted and open colectomy for colon cancer. N Engl J Med (2004) 350:2050-59.

of colon cancer with curative intent should be performed only by surgeons with experience with at least 20 procedures for benign disease.[47]

This episode demonstrates the relevance of case reports and case series to medical researchers and professionals. In retrospect, it appears that, in an attempt to allow patients to benefit from minimally invasive techniques, some surgeons did not fully comply with accepted oncologic principles in colon cancer operations and may have taken short-cuts with the extent of resection. The initial case reports were instrumental in identifying the issue of tumor recurrence and in prompting both further investigation and also significant policy change by two national surgical societies.

The example of laparoscopic procedures for colon cancer has a direct parallel to the instant case. The review article by Johnstone et al., describing 35 cases of port-site recurrences after laparoscopic colectomy for colon cancer,[48] was instrumental in compiling multiple case reports and small case series and indicating the existence and growing nature of the problem. Similarly, a case report by Jafek et al. was important in alerting medical professionals to the

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[47] American Society of Colon and Rectal Surgeons. Approved statement: laparoscopic colectomy for curable cancer. Dis Colon & Rectum (2004) 47(8):A1; American Society of Colon and Rectal Surgeons. Approved statement: laparoscopic colectomy for curable cancer. Surg Endosc (2004) 18(8):A1.

[48] Johnstone PA, Rohde DC, Swartz SE, Fetter JE, Wexner SD. Port site recurrences after laparoscopic and thoracoscopic procedures in malignancy. J Clin Oncol (1996) 14(6):1950-56.

risks of Zicam.[49] In addition, Davidson et al. published a report and review article describing 25 patients who developed acute-onset permanent anosmia after intranasal application of zinc gluconate gel.[50] In addition to the 25 cases observed in their institution, they reviewed other cases noted in the literature, bringing the total number of reported cases to 88. Just as Johnstone et al. recognized port-site recurrences as an unusual phenomenon after surgery for colon cancer, medical researchers also recognized the rare nature of acquired permanent anosmia and collated evidence to suggest a common causative agent. Thus, the example of Zicam and anosmia illustrates the importance of case reports and case series to medical professionals in providing material information that can justify further action.

In sum, medical professionals and researchers do not limit the data they consider to the results of randomized clinical trials or to statistically significant evidence. Rather, they take into account all medically relevant data. Accordingly, statistical significance should not be used as a rigid standard for defining the materiality requirement for reasonable investors in the context of medical risks.

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[49] Jafek BW, Linschoten MR, Murrow BW. Anosmia after intranasal zinc gluconate use. Am J Rhinol (2004) 18(3):137-41.

[50] Davidson TM, Smith WM. The Bradford Hill Criteria and Zinc-Induced Anosmia: A Causality Analysis. Arch Otolaryngol Head Neck Surg (2010) 136(7):673-76.

CONCLUSION

The judgment below should be affirmed.

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November 2010

AMICUS CURIAE BRIEF

No. 09-1156

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IN THE
Supreme Court of the United States

MATRIXX INITIATIVES, INC., ET AL.,
Petitioners,

v.

JAMES SIRACUSANO AND NECA-IBEW PENSION FUND,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

BRIEF OF *AMICI CURIAE* ECONOMISTS ROBERT E. LITAN AND JOSEPH R. MASON IN SUPPORT OF RESPONDENTS

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INTEREST OF AMICI CURIAE[1]

Amici are professors and academics who teach and write on financial economics. *Amici* wish to ensure that the Court properly assesses the economic costs and benefits of disclosure rules regarding adverse drug events in *Matrixx Initiatives, Inc. et al.* v. *James Siracusano and Neca-Ibew Pension Fund*. *Amici* have no stake in the outcome of this case. They are filing this brief solely as individuals and not on behalf of the institutions with which they are affiliated.

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[1] Pursuant to Supreme Court Rule 37.6, counsel for *amici* represent that no counsel for a party authored this brief in whole or in part and that none of the parties or their counsel, nor any other person or entity other than *amici* their members, or their counsel, made a monetary contribution intended to fund the preparation or submission of this brief. Counsel for *amici* also represent that all parties have consented to the filing of this brief, and letters reflecting their blanket consent to the filing of *amici* briefs have been filed with the Clerk.

antitrust matters. Dr. Litan also has served in several capacities in the federal government. During 1995 and 1996, he was Associate Director of the Office of Management and Budget (where he was responsible for overseeing budgetary and other policies of six cabinet agencies). From 1993 to 1995, he was Deputy Assistant Attorney General, in charge of civil antitrust litigation and regulatory issues, at the Department of Justice. From 1977 to 1979, he was the regulatory and legal staff specialist at the President's Council of Economic Advisers. In the early 1990s, Dr. Litan was a Member of the Commission on the Causes of the Savings and Loan Crisis. During his career, Dr. Litan has authored or co-authored over 20 books, edited another 14, and authored or co-authored over 200 articles in journals, magazines, and newspapers on a broad range of public policy issues. Dr. Litan received his B.S. in Economics, summa cum laude, from the Wharton School of Finance at the University of Pennsylvania; his J.D. from Yale Law School; and both his M. Phil. and Ph.D. in Economics from Yale University.

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INTRODUCTION

Petitioner Matrixx Initiatives Inc., manufacturers Zicam cold medicines, some of which have been alleged to cause anosmia—that is, loss of the sense of smell. Petitioners have argued that a statistical significance standard should be used to determine whether undisclosed adverse events are materially important in Section 10(b) cases. Under such a standard, a complaint would have to demonstrate that the rate of undisclosed adverse events among users of a drug exceeds, *in a statistically significant sense*, the benchmark rate.[2] Petitioners support such a standard by arguing that the statistical significance standard would mandate disclosure of any information that would be relevant to the financial marketplace in securities litigation.[3] However, adverse events may well be material to investors even when they are not statistically significant. As academic

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[2] Brief for Petitioner at 34, Matrixx Initiatives Inc., et al., v. James Siracusano and NECA-IBEW Pension Fund U.S. (No 09-1156).

[3] *Id.*

and practicing economists, we therefore disagree with the Petitioners.

SUMMARY OF ARGUMENT

Full and timely disclosure of adverse drug events is likely to benefit investors in financial markets. These benefits can be enjoyed without the imposition of additional reporting burdens on drug companies or the possibility of flooding financial markets with excessive information.

The U.S. Food and Drug Administration (FDA) currently requires drug companies to report all serious, unexpected adverse drug experiences, from both prescription and non-prescription medications as well as dietary supplements, within 15 calendar days of becoming aware of the event. Hence, full disclosure can be achieved without any new reporting burdens for drug manufacturers, as firms already have in place systems to collect and report these data. Moreover, such information would be absorbed by investors, who already respond to immense quantities of data from a variety of public and private sources. Therefore, arguments that full disclosure of adverse events would be either overly-burdensome to manufacturers or would flood investors with superfluous information are misguided.

A statistical significance requirement, by altering the incentives facing managers and other corporate insiders, could have unintended consequences. Drug companies could have an incentive to withhold information about adverse drug events to protect the firm's market share or share price. A statistical significance requirement could also lead to increased scrutiny of the behavior of insiders, which could increase speculation and volatility in financial markets.

ARGUMENT

I. Full Disclosure of Adverse Drug Events Is Unlikely to Be Harmful to Markets or Drug Companies

Requiring full disclosure of adverse drug events will not create a significant burden for drug companies, which are already required by law to report adverse events to the FDA in the form of Adverse Event Reports (AERs). Financial markets would not be harmed by any additional disclosures because investors already have access to vast quantities of information from a plethora of sources when making their investment decisions.

A. Drug Companies Are Currently Required to Disclose Adverse Drug Events

Opponents of the disclosure of Adverse Drug Reactions (ADRs) to financial markets might argue that such reporting would be costly and overly burdensome. To understand the flaws in this argument in general and with regard to the particular case at hand, one must first understand current and historic requirements of the disclosure of ADRs. Currently, drugs that are not marketed under new drug applications (NDAs) are subject to 21 C.F.R. § 310.305 for prescription, and 21 U.S.C. §§ 379aa(e) for over-the-counter (OTC), drugs. According to 21 C.F.R. § 310.305, manufacturers, packers and distributors of prescription drugs are required "to establish and maintain records and make reports to FDA of all serious, unexpected adverse drug experiences associated with the use of their drug products" within 15 calendar days of becoming aware of the event. More-

over, records of adverse events must be kept for at least six years.[4]

Public Law 109-462 requires reporting responsibilities for non-prescription medications and dietary supplements that are similar to reporting standards of prescription drugs.[5] Both prescription and OTC drugs marketed under a new drug application must adhere to stricter reporting guidelines. These standards include periodic filings of any adverse drug events.[6]

The requirements described above concern the *current* reporting standards to which a manufacturer of prescription pharmaceuticals or OTC medicines or supplements must adhere. Because Public Law 109-462—the Law requiring reporting of adverse events for OTC products—was not enacted until 2006, Matrixx was not required to report to the FDA adverse events involving Zicam products that occurred during the relevant period of this case. As such, any argument that public reporting of AERs would be overly burdensome to manufacturers *on a going forward basis* is immaterial to this particular matter. That is, Matrixx did not disclose Zicam-related AERs to the FDA, presumably because it was not required to at the time. Instead, the question here is whether Matrixx (1) attempted to hide material information from

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[4] 21 U.S.C. §§ 379aa(e).

[5] Regulations governing OTC products and dietary supplements are available via Food and Drug Administration, MedWatch, Reporting Serious Problems to the FDA, OTC Products and Dietary Supplements, available at http://www.fda.gov/Safety/MedWatch/HowToReport/ucm085680.htm. Public Law 109-462 is available at http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/ucm102797.pdf.

[6] *See* 21 C.F.R. § 314.80.

investors, such as reported instances of anosmia and specific, pointed warnings of a Zicam-anosmia link by specialists in the field, and (2) consequently, made misleading statements about Zicam products. Matrixx did not even have to consider the costs (such as clerical costs, for example) of mandatory disclosure of Zicam-related AERs.

Finally, a lack of a bright-line standard of significance for materiality of undisclosed AERs would not result in overly burdensome disclosure costs—for example, the need to incur burdensome costs to disclose AERs in periodic financial statements. As stated above, manufacturers of prescription drugs and OTC medicines and supplements are *currently* required to disclose adverse events to FDA. Therefore, any *additional* disclosure costs that might be borne by drug companies should be minimal, as these firms are already familiar with the practice. Moreover, separate reporting of AERs from what is already mandated by law may be unnecessary in many circumstances, as the FDA releases publicly available quarterly reports through its Adverse Event Reporting System (AERS).[7] This may further reduce any perceived burdens in timely disclosure of ADRs to the financial marketplace.

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[7] Food and Drug Administration, Potential Signals of Serious Risks/New Safety Information Identified from the Adverse Event Reporting System (AERS), Quarterly Reports, http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm082196.htm#QuarterlyReports.

B. Investors Already Respond to Massive Amounts of Information when Making Investment Decisions

The disclosure of ADRs to financial markets is unlikely to burden investors with excessive data that could cloud decision-making or harm the markets in general. Investors already have access to large quantities of data and information when making their decisions to buy, sell or hold securities. All public companies, foreign and domestic, whose securities are publicly registered for trading in the United States are required to file registration statements, periodic reports, and other forms with the Securities and Exchange Commission (SEC), which makes this information freely available on its website.[8] Accordingly, investors already have a wide array of financial data, market statements and other information disclosed by publicly traded companies themselves that such investors can use to formulate investment decisions.

Company filings and statements are not the only free source of information available to investors. Considerable information is collected and disseminated on multiple websites that do not charge for content. Examples include *Yahoo!Finance*, *CNN Money*, and *Bloomberg*. These websites allow for the download of historic stock data, market indices and other corporate data. They provide periodic investment reports and columns, sometimes by noted authors.

In addition to the free data and reports readily available to investors, numerous financial reports track specific types of market dynamics and pheno-

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[8] Securities and Exchange Commission, Filings & Forms, http://www.sec.gov/edgar.shtml.

mena within virtually any particular industry. These reports are drafted by private analysts and are available for purchase, with individual reports routinely costing hundreds or thousands of dollars.[9] Such a price premium on information over and above what is already provided freely to investors supports the notion that markets can bear more information. Given the incredible amount of data and analysis that is already available for free, investors would not pay for more data and more analysis unless they were able to use it in whole or in part to formulate more intelligent investment decisions.

Information regarding ADRs is already free and publicly available on the FDA's website. This information, which covers adverse event reports for prescription drugs, is updated quarterly. The FDA has used this reporting method since 1969.[10] Indeed, in the past decade, the FDA has entered 3,183,922 reports into its AERS database (through the first quarter of 2010).[11] Presumably, investors and securities

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[9] For an example of the availability of industry reports regarding over-the-counter drugs, see MarketResearch.com, Over-the-Counter Drugs Market Research Reports, available at http://www.marketresearch.com/browse.asp?categoryid=183.

[10] The Adverse Event Reporting System (AERS) contains over four million reports of adverse events and reflects data from 1969 to the present. Food and Drug Administration, Adverse Event Reporting System (AERS) Statistics, http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm070093.htm.

[11] Data describing the number and type of reports received and entered by the FDA is available at Food and Drug Administration, Reports Received and Reports Entered into AERS by Year, http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm070434.htm. The FDA notes that "these data are presented at the individual re-

analysts have analyzed these data and have incorporated them into their investment decisions. Therefore, it is untenable to argue that ADR reporting could provide harmful and superfluous data to investors.

Finally, the ultimate determinant of materiality in a securities matter could be whether information or data in question, once disclosed, results in a meaningful decrease in share price. Not only is there legal precedent for this standard,[12] but this is also the basic standard used within the field of finance. That is, if information is material to the stock in question, then the revelation of that information to the market, assuming that the market is efficient, would result in a significant "abnormal return."[13] Put simply, the stock price would change in a manner that could

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port level; some of the numbers may reflect duplicate reporting due to factors such as follow-up reports received on a case or different persons reporting on the same patient case."

[12] *See, e.g., No. 84 Employer-Teamster Joint Council Pension Trust Fund* v. *America West Holding Corp.*, 320 F.3d 920, 948 (9th Cir. 2003) (stating that "[s]tock price changes—or lack thereof--are also relevant to the determination of materiality"; adding that "[a]t a minimum, the static or dynamic nature of a stock price after the disclosure of previously withheld information is strong evidence of how reasonable investors view the significance of the information."); *In re Apple Computer Securities Litigation*, 886 F.2d 1109, 1116 (9th Cir. 1989) (stating that large price movements in response to public statements provide strong indication that the public statements were material).

[13] Abnormal returns are the returns of a stock price that cannot be explained by movement in a relevant index, be it a market index or a sector/industry index. Put differently, abnormal returns for a stock equal the difference between the actual returns on that stock and the returns predicted by a relevant index. *See, e.g.*, Zvi Bodie, Alex Kane, & Alan J. Marcus, Investments 368 (McGraw Hill, 2d ed. 1993).

not be explained away by comparable movements in a portfolio benchmark.

II. Full Disclosure of Adverse Drug Events Is Likely to Benefit Investors

Full disclosure would benefit investors by allowing them to make investment decisions from a more informed standpoint. In his seminal work, Professor Eugene Fama of the University of Chicago Booth School of Business described an efficient market as one in which "prices always 'fully reflect' available information." Eugene Fama, *Efficient capital markets: A review of theory and empirical work*, 25 Journal of Finance 383, 383 (1970). Different levels of market efficiency are distinguished by the amount of information that is reflected in the market price. According to the strongest form of efficiency, "prices reflect all the information that can be acquired by painstaking analysis of the company and the economy." Richard A. Brealy, Steward C. Myers & Franklin Allen, *Principles of Corporate Finance*, 359 (McGraw-Hill 2008). In a strongly efficient market, it would not be possible to consistently out-perform the market. Indeed, evidence on strong-form efficiency "has proved to be sufficiently convincing that many professionally managed funds have given up the pursuit of superior performance." *Id.* at 362.

The process by which markets determine which information is relevant and how prices should behave in response to relevant information is known as price discovery. The efficient-market hypothesis emphasizes that arbitrage will rapidly eliminate any profit opportunities and drive market prices back to fair value. *Id.* at 372. Markets and investors benefit from this process of price discovery, as capital markets

clear in equilibrium, leading to an efficient price such that market supply equals market demand. One benefit of efficient capital markets is that the market price generally will not deviate very far from this equilibrium price, thus helping to avoid sudden market crashes in the future. Another benefit is increased liquidity resulting from investors' confidence that they are not overpaying for a security. In an efficient market "you can trust prices, for they impound all available information about the value of each security." *Id.* at 373.

The mere presence of potentially irrelevant information does not affect outcomes in an efficient capital market. The market will decide whether an ADR conveys relevant information. For example, an ADR citing a minor headache as a side effect will not have the same effect on prices as an ADR showing that death occurred following consumption of a particular drug. Investors, including institutional investors, individual investors and large brokerage houses alike, are free to dispose of any available information that is not relevant to their investment decision. Investors sift through massive amounts of data from many sources every day, and there will be a natural filtering process, as investors decide what information is and is not relevant. Irrelevant information is discarded and thus does not affect an investor's portfolio choice. Moreover, particularly important information, regardless of whether it meets a specific standard of statistical significance, may be deemed relevant. Through this mechanism, markets will remain unaffected by irrelevant information and instead will focus on those factors determined to be worthy of consideration in making investment decisions.

III. A Statistical Significance Requirement Could Have Unintended Consequences

A potential problem with a statistical significance standard is that the power to perform a test in order to accept or reject unreported AERs as significant could fall into the hands of individuals who have a vested interest in the test's outcome. For example, decision-makers within a drug company may stand to benefit from postponing or under-disclosing adverse drug events. This may impact a drug company's behavior significantly, especially where the disclosure issue is perceived to be a "close-call." Furthermore, disclosure of only statistically significant reports would actually increase a stock's volatility and, thus, become even more potentially perilous to the financial markets.

A. A Statistical Significance Requirement Could Cause Drug Companies to Under-Disclose Adverse Drug Events

Disclosure of adverse drug events can lead to drug recalls, which usually result in significant declines in share prices.[14] For example, when Merck recalled the arthritis drug Vioxx in 2004, the company's stock price fell by more than $12 per share, reducing the value of the company by more than 25 percent.[15]

The potential negative effects of adverse drug events on the stock price and valuation of a firm has implications for the behavior of a firm's managers. This extends throughout the corporate organization,

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[14] Share price declines following drug recalls have been observed since the 1960s. *See* David Dranove and Chris Olsen, *The Economic Side Effects of Dangerous Drug Announcements*, 37 J. L. & Econ. 323, 323 (1994).

[15] *See* Marc Kauffman, *Merck Withdraws Arthritis Medication*, Wash. Post A01 (Oct. 1, 2004).

even where there is a formal division between the firm's business side and science side.

Managers' salaries are often tied to the short-term performance and profitability of the company. For many large companies, it is difficult to observe and measure the manager's performance. This information asymmetry and the resulting problem of motivating a manager to act in the best interests of the firm is known as the principal-agent problem. Tying the manager's compensation structure to overall company performance is a common solution to the principal-agent problem.[16] Cognizant of the effects of adverse drug effects on share prices, and given their own compensation tied to company performance, managers have an incentive to delay or under-disclose adverse drug events that could adversely affect short-term profits as well as investors' perceptions about future profitability. Each or both of these effects could reduce managers' compensation. A statistical significance standard to measure whether certain AERs are considered material would reinforce managers' incentives not to disclose, and specifically would introduce a bias into the conduct of any such test.

Insiders have a similar incentive to under-disclose adverse drug events, because they stand to lose a significant portion of their investment in the event that the publication of an adverse drug event negatively affects the stock price. With many firms now offering employee stock-purchase programs and com-

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[16] Solutions to the principal-agent problem, including "piece rates, options, discretionary bonuses, promotions, profit sharing, efficiency wages, deferred compensation", are outlined in Canice Prendergast, *The Provision of Incentives in Firms*, 37 J. Econ. Literature 7 (1999).

pany pension plans that invest in the company's own stock, an increasing number of employees have a vested interest in maintaining their company's stock price. Insiders with the power to influence whether and when to report an AER are likely to be more senior employees, who tend to hold larger volumes of shares. These are the insiders who stand to lose most from a share price decline. Consequently, a statistical significance standard of materiality may tempt these insiders to alter the reporting of AERs to their own financial gain.

B. A Statistical Significance Requirement Could Increase Market Volatility

A statistical significance requirement would provide incentive for insiders to sell their shares before the significance requirement is met. Specifically, a bright-line standard of statistical significance would encourage insiders to use AERs so that they may *predict* when a specific standard of significance will be met. By timing sales before such a standard is met, the insider avoids any loss from the resultant decrease in share price following a disclosure. As a result of this incentive, stock sales by insiders would be monitored more closely by industry analysts. Analysts may be concerned that sales of large quantities of shares by insiders, particularly if the timing coincides with third-party accounts of possible but yet officially unreported AERs, are evidence that a significant AER is imminent. This likely would increase speculation and volatility in the markets.

In any event, where a statistical significance test threshold is met and disclosed, this would likely have a greater market impact than when any particular number of AERs is reported. This impact would result in greater market volatility as investors sudden-

ly become aware that a large set of AERs were disclosed. A significant correction to prices would follow, as the market responded to the new information. By comparison, a gradual release of AER-related information allows investors to periodically adjust their expectations of significance in both a statistical and economic sense.

CONCLUSION

Full disclosure of adverse drug experiences is unlikely to be overly burdensome for drug companies, which already report such experiences to the FDA. Full disclosure is also unlikely to burden investors, who already process considerable quantities of information from a plethora of sources. In contrast, investors would benefit from full disclosure, which would facilitate informed decision-making. A statistical significance requirement could have unintended consequences and should be considered with caution. For these reasons, the judgment of the Court of Appeals for the Ninth Circuit to reverse the judgment of the District Court should be affirmed.

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AMICUS CURIAE BRIEF

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On Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

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BRIEF OF NATURAL PRODUCTS ASSOCIATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

The Natural Products Association (NPA) respectfully submits this brief as *amicus curiae* in support of Petitioners.

INTEREST OF THE *AMICUS CURIAE*

Founded in 1936, NPA is the nation's largest and oldest non-profit organization dedicated to the natural products industry.[1] NPA represents more than 10,000 retailers, manufacturers, wholesalers, and distributors of natural products, including a wide array of consumer goods that continue to grow in popularity each year. Among these products are natural and organic foods, dietary supplements, pet foods, health and beauty products, "green" cleaning supplies, and more. Generally, natural products are considered to be those formulated without artificial ingredients and that are minimally processed.

NPA is recognized for its strong industry presence in Washington, D.C., where it serves as a watchdog on regulatory and legislative issues. As relevant to

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[1] The parties have consented to the filing of this Brief. The written consent of Petitioners to the filing of briefs *amicus curiae* in support of either party or no party was filed with the Court on July 30, 2010. The written consent of Respondents to the filing of briefs *amicus curiae* in support of either party or no party was filed with the Court on July 28, 2010. Pursuant to Supreme Court Rule 37.6, NPA states that no counsel for any party authored this brief in whole or in part, and no counsel for any party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than NPA made such a monetary contribution.

this case, NPA represents members engaged in the business of selling, manufacturing, and distributing dietary supplements, which are regulated under federal law. *See* Dietary Supplement and Nonprescription Drug Consumer Protection Act ("2006 Act"), Pub. L. No. 109-462, 120 Stat. 3469 (2006); Dietary Supplement Health and Education Act of 1994 (DSHEA), Pub. L. No. 103-417, 108 Stat. 4325.

NPA (then known as the National Nutritional Foods Association) played a key role in the passage of the 2006 Act, which established the Adverse Event Report (AER) system. *See Statements on Introduced Bills and Joint Resolutions*, 152 Cong. Rec. S6285, S6287 (daily ed. June 21, 2006) (statement of Sen. Hatch). This legislation strikes a critical balance between the need for accurate information about "Serious Adverse Events" to be timely reported to the United States Food & Drug Administration (FDA) so that the agency may identify any worrisome signals in the reported data, and the equally important need to protect the industry and its customers from inaccurate, duplicative, or misinterpreted reports. The statute governs when and under what circumstances manufacturers, packers, and distributors of dietary supplements must provide Serious Adverse Event Reports (SAERs) to the FDA. *See* 21 U.S.C. § 379aa-1. Like the reporting law applicable to drug products, this statutory scheme contemplates that the FDA is the proper recipient of such information.

NPA has a direct interest in this litigation because the Ninth Circuit's ruling will undoubtedly extend beyond the pharmaceutical industry to other industries that are similarly required to report on certain adverse events. As such, the ruling poses a

significant threat to the dietary supplement industry and its consumers. The most central flaw in the decision is that it substitutes the judgment of securities fraud plaintiffs and their lawyers for the judgment of FDA scientists, thereby displacing Congress's carefully crafted reporting scheme.

The Ninth Circuit's approach would also vitiate other statutory protections that the 2006 Act provided to the dietary supplement industry, protections that are similar to ones provided to the "over the counter" (OTC) drug industry. In particular, Congress expressly provided that only *Serious* Adverse Events need to be reported to the FDA, and that SAERs "shall not be construed as an admission that the dietary supplement involved caused or contributed to the adverse event." 21 U.S.C. § 379aa-1(g). By allowing a case to survive a motion to dismiss based on a mere handful of AERs, the decision below overrides these statutory protections and threatens to inundate consumers with useless and potentially misleading information that offers no public-health benefit at all.

SUMMARY OF THE ARGUMENT

In the decision below, the Ninth Circuit held that Petitioner Matrixx Initiatives, Inc. ("Matrixx") had a duty under the securities laws to disclose AERs that it received from users of an OTC drug, Zicam. The court so held even though the AERs at issue were not alleged to constitute statistically significant evidence that the adverse events described were caused by Zicam. *Siracusano v. Matrixx Initiatives, Inc.*, 585 F.3d 1167, 1177-80 (9th Cir. 2009), *cert. granted*, 130 S. Ct. 3411 (2010). As Petitioners establish, the court's holding is erroneous under federal securities laws. In addition, the holding threatens to

undermine the statutory reporting system that Congress has established for manufacturers and distributors of dietary supplements, which in many ways resembles the reporting system for OTC products.

Similar to the requirements for OTC products, federal law requires manufacturers and distributors of dietary supplements to report all SAERs to the FDA. By statute, SAERs address Serious Adverse Events *associated with*, not *caused by*, dietary supplements. *See* 21 U.S.C. § 379aa-1(g). Congress expressly provided that SAERs could not be deemed admissions that a dietary supplement caused the reported Adverse Event. *Id.* § 379aa-1. Thus, the purpose of the statutory scheme is not to identify causation, but to enable the *FDA* to analyze SAERs associated with a particular dietary supplement across time and a number of consumers, in order to identify any signal that a health problem is associated with that supplement.

The Ninth Circuit's decision threatens to undermine Congress's careful scheme by effectively forcing manufacturers and distributors of dietary supplements to publicly disclose *all* AERs, not just SAERs, regardless of their weight or significance, and without the protections provided by Congress. The Ninth Circuit has held that a handful of individual AERs can be sufficient to survive a motion to dismiss and to impose on defendants the massive costs of class-action discovery. Issuers will not know in advance which insignificant AERs (out of the many thousands or more that are received) will be employed by enterprising plaintiffs' attorneys to initiate protracted litigation. As a result, to avoid the massive expense of defending or settling these suits, which are too often filed primarily for their nuisance

value, any entity required to maintain and report AERs will ultimately be compelled to publicly disclose *all* AERs.

In this way, the Ninth Circuit's approach is no better for consumers than it is for the industry. Because manufacturers and distributors of dietary supplements will likely need to publicly disclose all AERs in response to this holding, consumers will be flooded with worthless information. Congress's goal of improving the public health by allowing the FDA to inform the public about statistically significant signals will be all but lost in the confusion of statistically insignificant disclosures. Courts and plaintiffs' lawyers rather than the FDA will be left to determine the significance of such reports, contrary to the will of Congress. The Ninth Circuit's decision should be reversed.

ARGUMENT

I. CONGRESS HAS CRAFTED A CAREFULLY BALANCED SCHEME TO REQUIRE REPORTING OF SERIOUS ADVERSE EVENTS ASSOCIATED WITH DIETARY SUPPLEMENTS.

A. Federal Regulation Of Dietary Supplements.

A "dietary supplement" is defined by statute to include a vitamin, mineral, herb or other botanical, amino acid, "dietary substance for use by man to supplement the diet by increasing the total dietary intake," and a "concentrate, metabolite, constituent, extract, or combination" of any of these. 21 U.S.C. § 321(ff)(1). Prior to 1994, the FDA principally regulated dietary supplements under its general authority over food products. In 1994, however,

Congress created a regulatory regime applicable to dietary supplements as a distinct category of products by enacting DSHEA, Pub. L. No. 103-417, 108 Stat. 4325 (1994).

DSHEA focused both on accurate labeling of dietary supplements, *id.* secs. 5-7, §§ 403B, 403(r), (s), 108 Stat. at 4328-31, and on ensuring the safety of dietary supplements by authorizing the Secretary of Health and Human Services to initiate proceedings to remove a dietary supplement from the marketplace under certain conditions. *Id.* sec. 4, § 402, 108 Stat. at 4328. In particular, a dietary supplement may be removed under DSHEA if it is determined to be adulterated because it "contains any poisonous or deleterious substance which may render it injurious to health," "presents a significant or unreasonable risk of illness or injury," or is declared by the Secretary of the Department of Health and Human Services to "pose an imminent hazard to public health or safety." 21 U.S.C. § 342(a)(1), (f)(1)(A), (C).

In 2006, Congress supplemented this statutory regime through the Dietary Supplement and Nonprescription Drug Consumer Protection Act, Pub. L. No. 109-462, 120 Stat. 3469 (2006), by extending certain Adverse Event reporting requirements, already applicable to drugs and medical devices, to manufacturers of dietary supplements. Specifically, the statute requires manufacturers to file with the FDA SAERs documenting "any report received of a serious adverse event associated with such dietary supplement when used in the United States." *See* 21 U.S.C. § 379aa-1(a)(3), (b)(1). A "Serious Adverse Event" is a "health-related event associated with the use of a dietary supplement that is adverse," *id.* § 379aa-1(a)(1), and that

> (A) results in—(i) death; (ii) a life-threatening experience; (iii) inpatient hospitalization; (iv) a persistent or significant disability or incapacity; or (v) a congenital anomaly or birth defect; or (B) requires, based on reasonable medical judgment, a medical or surgical intervention to prevent an outcome described under subparagraph (A),

Id. § 379aa-1(a)(2). These requirements took effect December 22, 2007. 21 U.S.C. § 381 note.

The 2006 Act requires that all those subject to the SAER reporting requirement — called "responsible person[s]" under the statute — must submit to the Secretary any SAER "no later than 15 business days after the report is received." 21 U.S.C. § 379aa-1(c)(1). If a responsible person receives any new medical information related to a submitted SAER within one year of the initial report, that new information must likewise be submitted to the FDA within 15 days. *Id.* § 379aa-1(c)(2). Responsible persons submit required SAERs to the FDA through "MedWatch," FDA's system for post-market monitoring of drugs, food products, and supplements. *See* FDA, MedWatch: The FDA Safety Information and Adverse Event Reporting Program, www.fda.gov/safety/medwatch/default.htm; *see also* 21 U.S.C. § 379aa-1(d); FDA, *Guidance for Industry: Questions and Answers Regarding Adverse Event Reporting and Recordkeeping for Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act*, Question 11 (Oct. 2007; revised June 2009), http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/DietarySupplements/ucm171383.htm (hereinafter "*Guidance for Industry*"). The FDA also receives SAERs and AERs from third

parties, such as consumers and health care providers, also through the MedWatch system.

In addition to imposing reporting requirements on dietary supplement manufacturers and distributors, the 2006 Act simultaneously created substantial protections for the industry. First, and most significantly, the law explicitly recognizes that such reports are not proof that the adverse event was caused by a dietary supplement: "The submission of any adverse event report in compliance with this section shall not be construed as an admission that the dietary supplement involved caused or contributed to the adverse event." 21 U.S.C. § 379aa-1(g); *see also* FDA Form 3500A (MedWatch form, also providing that "[s]ubmission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event"), http://www.fda.gov/downloads/Safety/MedWatch/HowToReport/DownloadForms/UCM082728.pdf.

Rather, adverse event reporting merely allows the FDA to gather sufficient data to identify potential patterns that warrant more focused study. *See* S. Rep. No. 109-324, at 7 (2006) ("the intent of these new [SAER] systems is to alert officials about emerging problems with a product. ... [T]hese new systems are designed to generate signals which require further evaluation."). If the FDA determines, based on its aggregation of information, that a dietary supplement is a cause for significant concern, it issues an alert to inform both the public and the manufacturer of the issue. *See* FDA, Dietary Supplement Alerts and Safety Information, http://www.fda.gov/Food/DietarySupplements/Alerts/default.htm. As such, enforcement is, at least initially, in the hands of a federal agency with

expertise and a congressional mandate, not plaintiffs' attorneys with a strike suit and an economic incentive to impose unnecessary costs on the industry.

Second, in response partly to the concerns raised by the industry that plaintiffs' attorneys would misuse the AER system by bringing meritless litigation, Congress sought to ensure the integrity of the reporting scheme. Congress thus maintained the accuracy of the information submitted in SAERs by expressly prohibiting "[t]he falsification of a report of a serious adverse event submitted to a responsible person." 21 U.S.C. § 331(ii). Congress also made the intentional submission of a false SAER grounds for criminal penalties. *Id.* § 333(a). Finally, Congress granted the FDA authority to "issue guidance" to the industry on what "minimum data elements ... should be included in a serious adverse event report" in order to make SAERs complete and accurate for the agency's purposes. *Id.* § 379aa note.

B. The Legislative History Confirms That The AER Reporting Requirements Were Carefully Constructed To Provide Useful Information To FDA Regulators While Protecting Industry Members From Liability And Overly Burdensome Reporting.

The legislative history of the 2006 Act makes clear that Congress, with this legislation, took a measured and science-based approach to the issue of AER reporting by dietary supplement manufacturers and distributors. Citing the FDA's "substantial experience in administering adverse event reporting systems," S. Rep. No. 109-324, at 8, legislators crafted a system by which that agency, in its expertise, would be given authority to receive, review, and act on

SAERs as appropriate. Legislators made clear that the overall purpose of the new reporting requirement was to permit the agency to garner relevant information from across a spectrum of SAERs — that is, to "alert officials about emerging problems with a product" and to "generate signals" informing the agency about which reported events "require further evaluation." *Id.* at 7. In other words, "the intent of the new system is not to determine causality, but rather to provide the government with information about possible problems associated with the use of a supplement." *Id.* at 12.

In order to achieve these goals, legislators emphasized that the Act was deliberately crafted to ensure that only *useful* information would be required to be reported, and that over-disclosure that could prove burdensome and distracting to the industry, agency, and public would be specifically avoided. As the committee report makes clear, the legislation

> limit[s] the reporting requirement to the information FDA really needs: reports of death; a life-threatening experience; hospitalization; a persistent or significant disability or incapacity; a congenital anomaly or birth defect. In limiting the reporting system to serious events only, the committee recognizes that any broader reporting system could overburden manufacturers, consumers and the agency alike, generating information that may not be useful to the public health system at tremendous cost to all involved.

Id. at 6.

Relatedly, legislators described their firm recognition — reflected in the statute as codified, 21 U.S.C. § 379aa-1(g) — that no SAER was proof that

the dietary supplement at issue had caused any sort of harm. "The committee emphasizes that adverse events are communications from consumers regarding events that may be associated with the use of a dietary supplement or nonprescription drug. The fact of a report of an adverse event is not determinative that the event occurred or that the event was caused by a consumer's use of the product." S. Rep. No. 109-324, at 6. The Committee Report makes clear that responsible persons were required to submit SAERs to the FDA "whether or not the reporter sought medical care or otherwise had proof of a serious adverse event. Indeed, the committee notes that the MedWatch form, which the reporter must use under [the Act], explicitly directs consumers to 'Report, even if you're not certain the product caused the event' or 'you don't have all the details.'" *Id.* at 7.

Even so, legislators recognized that industry members had

> concerns that possible litigation may ensue from the fact that a report was filed, and that the report could be construed as an admission that the product "caused" the serious event. In response, the committee took great pains to make clear that the mere filing of a report will in no way indicate causation of the serious adverse event. To underscore that point, language is included in [the Act] indicating that the submission of an adverse event report in compliance with the bill's requirements shall not be construed as an admission that the nonprescription drug or dietary supplement involved caused or contributed to the adverse event or otherwise caused or contributed to a death, serious injury or serious illness.

Id. at 12. Legislators also considered, but expressly rejected, "requiring the FDA to prove" that a particular dietary supplement "caused the serious adverse event prior to accepting the report. Even if a system for proving the causality could be determined and agreed upon, proving that causality could be very costly and entail long delays in reporting, depriving public health officials of the valuable sentinel information inherent in a report." *Id.*

Legislators also sought to ensure that the agency would take action based only on accurate information. Although legislators sought "to encourage a broad reporting of all serious adverse events associated with" dietary supplements, they were "also sympathetic to concerns expressed that the potential for multiple reporting of the same event could artificially inflate the numbers of reports associated with a product," and that "incomplete reports could indicate a less-than-serious report is being made." *Id.* at 8-9.

Legislators accordingly "balanced two competing goals — the need to ensure as broad a reporting as possible of any serious adverse events against the cognizance that incomplete, false or duplicative reports could be harmful and costly to manufacturers, the FDA, and the public health." *Id.* at 8. The Act thus explicitly required the agency to "develop systems to ensure consolidation into a single report of both duplicate reports of a serious adverse event, and duplicate reports of additional medical information related to that event." *Id.* at 9. And, noting that the FDA had previously provided Adverse Event reporting guidance to producers of drugs and biological products, the Act thus called on the FDA likewise "to issue guidance on the minimum data elements that should be included in any serious

adverse event reports" in order to improve the accuracy and usefulness of those reports. *Id.* at 8.

Fulfilling that mandate, the FDA has made clear that an SAER is required to be submitted only if the manufacturer or distributor that received the report is able to obtain and include five essential data elements: an identifiable patient, an identifiable initial reporter, identity and contact information for the responsible person submitting the report, a suspect dietary supplement, and a serious adverse event or fatal outcome. *Guidance for Industry*, Question 13. FDA has declared that each of these data elements is necessary "to avoid duplication in its adverse event reports database, interpret the significance of adverse events, facilitate follow-up, and detect fraud." *Id.* In other words, in the agency's view, incomplete SAERs are insufficiently informative to assist the FDA in determining which SAERs indicate that further evaluation is necessary.

Once Congress had crafted the Act with its emphasis on FDA analysis and review of SAERs, and with its many and substantial protections for both consumers and dietary supplement manufacturers and distributors, the legislation found wide-ranging support among consumer groups and industry players alike. *See* 152 Cong. Rec. at S6287 (citing the support of, among others, NPA (then called the National Nutritional Foods Association), the Consumer's Union, the Center for Science in the Public Interest, the Consumer Healthcare Products Association, and the American Herbal Products Association). In the words of Senator Hatch, "[t]hat these groups, not often united — at least on this subject — can rally around our bill today is a testament to good policy, good politics, and a surviving bipartisan spirit." *Id.*

II. AFFIRMING THE NINTH CIRCUIT'S RULING WOULD DISRUPT THE CAREFUL LEGISLATIVE BALANCE EMBODIED IN THE 2006 ACT AND BROADLY THREATEN THE DIETARY SUPPLEMENT INDUSTRY.

The Ninth Circuit's decision, if affirmed, would dismantle the considered approach that Congress took — with the support of both consumer advocates and the dietary supplement industry — in the 2006 Act. The lower court's decision would permit plaintiffs' lawyers, through the vehicle of the securities laws, to allege that a small number of SAERs indicate that a dietary supplement has caused harm to consumers. Such an assertion could be made — and given credence by reviewing courts and juries — even though Congress expressly rejected the notion that SAERs have any such meaning in the 2006 Act. Moreover, such an assertion could be made even when the FDA, with its scientific expertise and its mission to protect the public health, has made no finding that SAERs associated with a particular dietary supplement raise any cause for concern.

Approving such an approach would impose substantial risks on the dietary supplement industry. That industry has been recognized by Congress as contributing extensively both to public health and to the economy. Yet securities law strike suits filed on the basis of insubstantial numbers of unsubstantiated SAERs could create massive costs for dietary supplement manufacturers and distributors — particularly smaller entities, which can ill afford the high costs of litigation — even if entirely meritless. To avoid such costs, manufacturers and distributors would likely be forced broadly to disclose all AERs, to the detriment of the industry, the FDA, consumers,

and the balance carefully calibrated by Congress with the 2006 Act.

A. The Ninth Circuit's Approach Is Inconsistent With The Express Provisions And Purpose Of The 2006 Act.

The 2006 Act expressly anticipates that the FDA will have responsibility for reviewing, and taking action as appropriate on, reports of serious adverse events associated with dietary supplements. It is the FDA to whom SAERs are submitted, and it is the FDA that is tasked with weighing and evaluating SAERs, in recognition that no SAER establishes that the Adverse Event at issue was caused by the identified nutritional supplement. *See* 21 U.S.C. § 379aa. As explained in Part I, *supra*, these fundamental principles are essential to the balanced approach that Congress took with the 2006 Act. And they were essential to securing the support of the dietary supplement industry, which expressed concerns that SAERs would be misinterpreted and would subject industry participants to groundless lawsuits. *See* p. 13, *supra*.

Nonetheless, the approach taken by the Ninth Circuit, if applied in the context of dietary supplements (and there is no reason to suppose it would not), would pay no regard to the expert opinion of the FDA, or to Congress's express limitations on the meaning of SAERs. In its opinion holding that Plaintiffs had stated a claim of securities fraud against Petitioners, the court expressly engaged in its own "fact-specific inquiry" into the Plaintiffs allegations as to the content and nature of AERs related to Zicam. *Siracusano*, 585 F.3d at 1179. The court made no mention of and paid no heed to whether the FDA had reviewed or taken action based on the same AERs, and likewise ignored the meaning

that such AERs would be given by the FDA. *See id.* In doing so, the Ninth Circuit chose to make for itself, rather than allowing the FDA to make, the "difficult policy choices that agencies are better equipped to make than courts." *Nat'l Cable & Telecomms. Ass'n v. Brand X Internet Servs.*, 545 U.S. 967, 980 (2005).

Notably, the Ninth Circuit expressly rejected the approach of the Second Circuit, which had, by contrast, taken account of the FDA's role in the AER reporting process:

> FDA regulations require that "all adverse drug experience information" be reported to the FDA. 21 C.F.R. § 314.80(c) (1999). Drug manufacturers receive these reports from several sources, including treating physicians. An "adverse drug experience" is defined broadly to include "[a]ny adverse event associated with the use of a drug in humans, *whether or not considered drug related.*" 21 C.F.R. § 314.80(a) (1999) (emphasis added).... Contrary to the appellants' assertions throughout their complaint, the receipt of an adverse report does not in and of itself show a causal relationship between [a drug] and the illness mentioned in the report.

In re Carter-Wallace, Inc. Secs. Litig., 220 F.3d 36, 40-41 (2d Cir. 2000). By ignoring the context in which such reports are made and submitted to the FDA, and by disregarding the treatment the FDA gives to such reports, the Ninth Circuit's approach distorts the objectives of Adverse Event reporting requirements and vitiates the expert role of the FDA in reviewing and analyzing those reports.

Indeed, that is precisely what happened in the case below. Plaintiffs' claim of securities fraud was based

on Petitioners' alleged failure to disclose AERs from 12 to 23 consumers of Zicam.[2] *Siracusano*, 585 F.3d at 1179; *see also* Pet. 4 & n.1. During the class period at issue in the Complaint, October 2003 through February 2004, the *FDA had taken no action* with regard to Zicam based on AERs received, *see Siracusano*, 585 F.3d at 1169-70 & n.1, although pharmaceuticals manufacturers (like dietary supplement manufacturers and distributors) are required to submit AERs to that agency. *See* 21 C.F.R. § 314.80.

In other words, the AERs submitted to that date were not sufficient to cause the agency to conclude that Zicam was causing adverse events. The FDA did not conclude that action was warranted until it had received "more than 130 reports of anosmia" by users of Zicam — in June 2009. *See* FDA, Warnings on Three Zicam Intranasal Zinc Products, http://www.fda.gov/forconsumers/consumerupdates/ucm166931.htm. Thus, even though the agency most expert in the regulation of such products first concluded that Zicam was associated with adverse events only after receiving some 130 AERs, the Ninth Circuit's approach here allowed Plaintiffs' lawyers to short-

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[2] The uncertainty as to the number of consumers at issue derives from plaintiffs' failure to identify whether the reports relied on in their Complaint include duplicate reports of the same adverse events. *See* Pet. 4 & n.1. Notably, the issue of duplicate reports was a concern explicitly addressed by Congress in its establishment of the SAER system for dietary supplements. *See* S. Rep. No. 109-324, at 9 (discussing "concerns ... that the potential for multiple reporting of the same event could artificially inflate the numbers of reports associated with a product"); 21 U.S.C. § 379aa-1(c)(3) ("The Secretary shall develop systems to ensure that duplicate reports of, and new medical information related to, a serious adverse event shall be consolidated into a single report.").

circuit the agency's review process, bringing suit based on the alleged nondisclosure of a mere 12 to 23 statistically insignificant reports.[3]

In short, the Ninth Circuit allowed the agency's judgment to be supplanted by that of the Plaintiffs and their attorneys. Affirming the approach taken by that court could expose participants in all industries subject to similar adverse event reporting requirements to the same result, regardless of the statutory protections conferred on them by Congress.

B. Allowing The Judgment Of The Ninth Circuit To Stand Would Impose Massive Risks On The Dietary Supplement Industry.

In particular, the Ninth Circuit's approach could wreak havoc in the dietary supplement industry. Congress has expressly recognized both the value of dietary supplements to Americans' public health, and the importance of dietary supplements to the national economy. As Congress found, "the importance of nutrition and the benefits of dietary supplements to health promotion and disease prevention have been documented increasingly in scientific studies." DSHEA, § 2(2), 108 Stat. at 4325. "[T]here is a link

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[3] As petitioners explain (Br. at 46), the handful of AERs cited by plaintiffs were "received over the course of four years . . . when Matrixx sold literally *millions* of units of Zicam." Moreover, nowhere in the complaint do plaintiffs "compare that trivially miniscule reported incident rate to the known incident rate of anosmia in the population – and in particular, in the population of people who have colds, and thus take remedies like Zicam." *Id* (emphasis omitted). Virtually every (if not, in fact, every) widely marketed over-the-counter drug will be connected with at least some AERs. The complaint does not reflect any analysis showing that the AERs at issue were statistically significant.

between the ingestion of certain nutrients or dietary supplements and the prevention of chronic diseases such as cancer, heart disease, and osteoporosis," such that "healthful diets may mitigate the need for expensive medical procedures, such as coronary bypass surgery or angioplasty." *Id.* § 2(3)(A), (4), 108 Stat. at 4325-26. Indeed, "preventive health measures, including education, good nutrition, and appropriate use of safe nutritional supplements will limit the incidence of chronic diseases, and reduce long-term health care expenditures." *Id.* § 2(5), 108 Stat. at 4326. Congress found that, as of 1994, "almost 50 percent of the 260,000,000 Americans regularly consume dietary supplements of vitamins, minerals, or herbs as a means of improving their nutrition." *Id.* § 2(9), 108 Stat. at 4326.

That level of demand had made "the nutritional supplement industry ... an integral part of the economy of the United States," with "the estimated 600 dietary supplement manufacturers in the United States produc[ing] approximately 4,000 products, with total annual sales of such products alone reaching at least $4,000,000,000." *Id.* § 2(12)(A), (C), 108 Stat. at 4326. These numbers have dramatically increased in the years since DSHEA's enactment in 1994: as of 2006, the value of the dietary supplement industry was estimated to be approximately $20 billion, 152 Cong. Rec. at S6286, while today it is over $25 billion. *See* NPA, About the Natural Products Association, http://www.npainfo.org/index.php?submenu=About&src=gendocs&ref=AboutNPA&category=About (citing Nutrition Business Journal).

However, many players in that industry face the risk of substantial losses through baseless securities litigation if the Ninth Circuit's decision is upheld. In recognition of the potential costs imposed by such

litigation, this Court has repeatedly emphasized the need for sound rules to govern and constrain private securities-fraud lawsuits. In the absence of such rules, meritless securities litigation can be employed "abusively to impose substantial costs on companies and individuals whose conduct conforms to the law." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 313 (2007). "[P]laintiffs with weak claims [can] extort settlements from" companies that are innocent, but that nevertheless fear "extensive discovery and the potential for uncertainty and disruption in a lawsuit." *Stoneridge Inv. Partners, LLC v. Scientific-Atlanta, Inc.*, 552 U.S. 148, 163 (2008); *see also Merrill Lynch, Pierce, Fenner & Smith Inc. v. Dabit*, 547 U.S. 71, 80-81 (2006).

The risk that such suits will force even innocent companies to settle the litigation is well-recognized. According to one study, almost 100 private securities suits settled for a total value of $3.6 billion in 2008 alone. *See* PriceWaterhouseCoopers, *2008 Securities Litigation Study* 18 (Grace Lamont ed., 2009), *available at* http://10b5.pwc.com/PDF/NY-09-0894%20SECURITIES%20LIT%20STUDY%20FINAL.PDF. Settlement is often a near requirement for defendants in such lawsuits, because of the huge costs of the discovery process when a claim is permitted to proceed beyond a motion to dismiss. *See Blue Chip Stamps v. Manor Drug Stores*, 421 U.S. 723, 741 (1975); *see also Cent. Bank of Denver v. First Interstate Bank of Denver*, 511 U.S. 164, 189 (1994) ("uncertainty [in] the governing rules" could prompt companies, "as a business judgment, to abandon substantial defenses and to pay settlements in order to avoid the expense and risk of going to trial").

In light of these "practical consequences" of liberal treatment of securities fraud suits, *see Stoneridge*,

552 U.S. at 156-63, this Court has consistently counseled the application of rules that provide "'certainty and predictability'" in this area. *Cent. Bank*, 511 U.S. at 188 (quoting *Pinter v. Dahl*, 486 U.S. 622, 652 (1988)). The Court has thus rejected "shifting and highly fact-oriented disposition[s]," which do not provide "a satisfactory basis for a rule of liability imposed on the conduct of business transactions." *Id.* (internal quotation marks omitted).

The Ninth Circuit's approach, however, expressly calls for just the sort of "fact-specific inquiry" that this Court has criticized. *See Siracusano*, 585 F.3d at 1179. Indeed, it allows securities fraud plaintiffs to proceed to discovery based on a string of "facts" — that is, individual AERs — that, in the context of dietary supplements, Congress has declared immaterial as a matter of law. In doing so, the Ninth Circuit has exposed all manufacturers and distributors of dietary supplements — as well as participants in other industries subject to AER reporting requirements — to the massive expense and risk of securities litigation. Irrespective of whether the FDA, the agency charged with reviewing SAERs, finds the reports remotely significant, the plaintiffs' bar will be able to shake down the industry with factbound, resource-intensive strike suits.

The risk of harm posed by such strike suits is particularly grave for small and independent producers of dietary supplements. Like all dietary supplement manufacturers and distributors, small firms are required to report Serious Adverse Events. Yet smaller issuers have less capacity to bear the costs of securities litigation, and would face even

more heightened pressure to reach settlement.[4] In the process of enacting the DSHEA, Congress specifically recognized the dire consequences that "baseless lawsuits" pose to small dietary supplement manufacturers: Being forced to face such litigation "subject[s] small manufacturers to the choice of abandoning production and sale of lawful products, or accepting the significant financial burden of defending themselves against baseless lawsuits." S. Rep. No. 103-410, at 21 (1994).

In order to avoid the extensive costs of such litigation, manufacturers and distributors of dietary supplements would likely be forced into the position of over-disclosing. That is, they could manage to avoid a result like that reached by the Ninth Circuit with any certainty only by indiscriminately publicly disclosing every AER that they received. Yet such a result would be highly burdensome, would be to the detriment of both the FDA and the public, and would be directly contrary to the intent of Congress in enacting the 2006 Act. Congress simply did not intend the industry to inundate consumers with useless, immaterial information that is of no value to any purchasing decision.

To the contrary, legislators were highly sensitive to the problems that could be caused by over-disclosure if the SAER reporting requirements established in the 2006 Act were not carefully balanced. First, Congress "limit[ed] the reporting system to serious events only" based on its "recogni[tion] that any broader reporting system could overburden

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[4] Further, to the extent that the Ninth Circuit's flawed materiality analysis made its way into contexts other than securities litigation (for example, products liability), the litigation exposure would increase exponentially.

manufacturers, consumers and the agency alike, *generating information that may not be useful to the public health system at tremendous costs to all involved.*" S. Rep. No. 109-324, at 6 (emphasis added). Second, Congress required reporting only to the FDA, which could make a reasonable, scientifically based decision, relying on its expertise and concern for the public interest. Congress did not require disclosure to the SEC, let alone directly to the public and plaintiffs' attorneys who could bring nuisance suits based on erroneous allegations that are costly to disprove.

Unlike the FDA, public consumers of dietary supplements are not well-versed in the limited informational value of individual SAERs. As explained above, p. 6-8, *supra*, an SAER indicates only that an adverse event is *associated with*, not *caused by*, a dietary supplement. *See* 21 U.S.C. § 379aa-1(a)(1). Indeed, consumers are encouraged to report an Adverse Event even if they are "'not certain the product caused the event'" or "'don't have all the details.'" S. Rep. No. 109-324, at 7. Thus, an Adverse Event might be reported based on something completely irrelevant – for example, a traffic fatality that occurred soon after the driver ingested a dietary supplement, even though the accident could have resulted from countless causes.

Unbridled public disclosure of SAERs would provide consumers with no assistance in sorting through and analyzing the disclosures for their significance. In all likelihood, consumers unfamiliar with the limitations on Adverse Event reporting may well take SAERs to have far greater significance than in fact they do. Consumers might thus decline to use a dietary supplement based on statistically insignificant information — even though, as Congress

has found, the use of supplements is highly beneficial to the public health. *See* DSHEA § 2, 108 Stat. at 4325. Such a result would entirely defeat the purpose of the 2006 Act — namely to enable FDA scientists to analyze SAERs in the aggregate in order to identify any statistically significant signals or trends, and to educate the public of the results of their considered and expert review. *See* S. Rep. No. 109-234, at 6-7.

CONCLUSION

For the foregoing reasons, and those stated in Petitioners' Brief, the judgment of the court of appeals should be reversed.

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AMICUS CURIAE BRIEF

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Petitioners,

v.

JAMES SIRACUSANO AND
NECA-IBEW PENSION FUND,
Respondents.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

BRIEF FOR THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AND THE BIOTECHNOLOGY INDUSTRY ORGANIZATION AS AMICI CURIAE SUPPORTING PETITIONERS

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INTEREST OF AMICI CURIAE

The Pharmaceutical Research and Manufacturers of America (PhRMA) is a voluntary, nonprofit association that represents the country's leading research-based pharmaceutical and biotechnology companies.[1] PhRMA's members are dedicated to discovering medicines that enable patients to lead longer, healthier, and more productive lives. Member companies are the source of a majority of all new medicines. New medicines account for 40 percent of the increase in human lifespan between 1986 and 2000. *See* Lichtenberg, Nat'l Bureau of Econ. Research, Working Paper No. 9754, *The Impact of New Drug Launches on Longevity: Evidence From Longitudinal, Disease-Level Data From 52 Countries, 1982-2001*, at 21 (2003). Pharmaceutical companies, including PhRMA's members, have invested approximately $300 billion in the last decade to develop new medicines—including over $65 billion in 2009 alone. *See* PhRMA, *Pharmaceutical Industry Profile 2010*, at 26 (2010), at www.phrma.org/sites/phrma.org/files/attachments/Profile_2010_FINAL.pdf.

The Biotechnology Industry Organization (BIO) is the world's largest biotechnology organization, providing advocacy, business development, and communications services for more than 1,100 members worldwide.

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[1] Counsel for both parties have filed letters consenting to the filing of all amicus briefs. No counsel for a party authored any part of this brief, and no person or entity other than members of or counsel for PhRMA and BIO made a monetary contribution to the preparation or submission of this brief. A list of PhRMA's members is available at http://www.phrma.org/member_company_list. A list of BIO's members is available at http://www.bio.org/members/biomembers.asp.

BIO members are involved in research and development of innovative healthcare technologies, as well as biotechnology applications in the agriculture, energy, and environmental sectors. Corporate members range from entrepreneurial companies developing a first product to Fortune 100 multinationals. BIO also represents state and regional biotechnology associations, service providers to the industry, and academic research centers.

PhRMA and BIO members closely monitor legal issues that affect the biopharmaceutical industry, and PhRMA and BIO have frequently participated in cases before this Court raising such issues. *See* Briefs filed by PhRMA and/or BIO in *Merck & Co.* v. *Reynolds*, 130 S. Ct. 1784 (2010) (No. 08-905); *Wyeth* v. *Levine*, 129 S. Ct. 1187 (2009) (No. 06-1249); *Warner-Lambert Co.* v. *Kent*, 128 S. Ct. 1168 (2008) (No. 06-1498); and *eBay Inc.* v. *MercExchange, LLC*, 547 U.S. 388 (2006) (No. 05-130).

The issue in this case is especially significant to PhRMA and BIO members because a number of members have borne the expense and burden of defending against securities fraud class actions in recent years. In 2008 and 2009, for example, over 40 such actions were filed against pharmaceutical and biotechnology companies. Dechert LLP, *Dechert Survey of Securities Fraud Class Actions Brought Against Life Sciences Companies* 2 (Mar. 2010), at www.dechert.com/library/3-10_WCSL_Kotler_Survey_of_Securities_Fraud_CA.pdf. These suits, which are often filed for their nuisance value, raise the already substantial costs and risks associated with the development of new medicines. The erroneous approach taken by the Ninth Circuit in this case is of serious concern to PhRMA and BIO members, as it makes it unnecessarily difficult, if

not impossible, for defendants in securities lawsuits to secure prompt dismissal of claims that rest only on a supposed failure to disclose information that would not affect the sales or profitability of the company. Such litigation accordingly threatens the ability of biopharmaceutical companies, including PhRMA's and BIO's members, to research and develop new medical advances.

SUMMARY OF ARGUMENT

A collection of adverse event reports that is not statistically significant does not permit a reasonable inference that a particular medicine actually *caused* the reported adverse event. Standing alone, such reports would not reasonably affect a biopharmaceutical manufacturer's earnings and, accordingly, are not material under the securities laws. Before the Ninth Circuit's decision, every Circuit to address the question presented had recognized as much. The decision below, however, departs from that well-reasoned principle while failing to supply any alternative standard whatsoever. The Ninth Circuit's ruling is all the more troubling because such a standardless test for materiality may compel manufacturers to over-disclose adverse event reports or studies that have no bearing on financial performance, lest they be accused of making misleading market statements about their products. In addition to being unduly burdensome, the resulting excessive disclosure of statistically insignificant adverse event reports will lead to investor confusion and stock fluctuation, which will harm manufacturers and their investors, as well as consumers and patients, who may be deterred from using safe and effective treatments.

This Court should endorse the approach taken by the Second Circuit and adopted by the First and Third

Circuits and several district courts: adverse event reports or studies known to a biopharmaceutical manufacturer, without more, cannot be material under the securities laws unless they establish a statistically significant link between the product and the adverse event. The statistical significance standard requires disclosure only once a correlation between an adverse event and the subject product can be reasonably inferred to be causal. It is only at that point that a manufacturer or regulatory body might react to adverse events, that a medicine's sales would be threatened, and that a rational investor might consider this information in making investment decisions.

The majority approach also properly recognizes that there may be limited circumstances in which statistically insignificant adverse event reports, together with other factors, demonstrate that a product's sales are threatened and a decline in sales of the drug would have a material effect on the biopharmaceutical manufacturer's earnings, such that the manufacturer is required to disclose adverse events that were not statistically significant. Absent such other indications of materiality, however, statistically insignificant adverse events standing alone are immaterial as a matter of law. Further, allegations of scienter also fail as a matter of law in such situations. A defendant can reasonably believe that statistically insignificant adverse event reports or studies (unaccompanied by additional indications of materiality) are immaterial.

This principle rests on the logical proposition that the sales and profitability of a medicine and the biopharmaceutical company that manufactures it are not threatened by adverse event reports from which no causal link can be inferred. Receipt of an adverse event report may be cause to investigate or inquire, but only

when adverse events become statistically significant is there a "substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having *significantly altered* the total mix of information made available," thus requiring disclosure. *Basic Inc.* v. *Levinson*, 485 U.S. 224, 231-232 (1988) (emphasis added, internal quotation marks omitted). Assuming that the securities markets are efficient and rational, as this Court's jurisprudence requires, a reasonable investor will view statistically insignificant reports as the ordinary state of affairs, not as a significant change in the total mix of information bearing on a rational investment decision.

Recognizing the importance of statistical significance is all the more appropriate given that raw adverse event data are already publicly available. Adverse event reports submitted to the U.S. Food and Drug Administration (FDA) by patients, medical professionals, and manufacturers are catalogued and published on the FDA's website at regular intervals. Any potential investor can examine these reports, and the efficient market is presumed to be aware of this information. The rule adopted by the First, Second, and Third Circuits accepts that this information is already publicly disseminated, and thus manufacturers should not be forced to bury investors with additional public speculation regarding the meaning of each adverse event report.

The Ninth Circuit's decision improperly rejects this approach while providing no workable alternative to it. Its consequence would be to overwhelm the market with meaningless data and flood the courts with unproductive litigation, contrary to the purpose of the securities laws. *See TSC Indus., Inc.* v. *Northway, Inc.*, 426 U.S. 438, 448 (1976). The result will be not investor

protection but investor confusion, unduly burdensome over-disclosure of immaterial information, and the needless proliferation of unfounded concerns among patients and consumers regarding correlations that do not suggest causation. This Court should reverse.

ARGUMENT

I. A Reasonable Investor Would Not Base Investment Decisions On Statistically Insignificant Reports Of Adverse Events, Which Are Unlikely To Threaten A Drug's Sales

A. The Wide Range Of "Adverse Event Reports" In The Biopharmaceutical Industry

An "adverse event report" in the biopharmaceutical industry refers to any report of a negative event in which a biopharmaceutical product was used or involved. An adverse event report could be an anonymous electronic message submitted via a company website, a telephone call from any source to the FDA, or a published clinical study by reputable scientists. Reports vary widely in their detail, reliability, verifiability, and neutrality. The FDA receives hundreds of thousands adverse event reports every year—many of which are determined to have no causal association whatsoever with the product in question.

The FDA collects and analyzes reports of adverse events in order to monitor the continued safety of the products it regulates. The FDA's own definition of "adverse event" is extremely broad, including even events that result from the misuse or abuse of drug products:

> Any adverse event associated with the use of a drug in humans, *whether or not considered drug related*, including the following: An ad-

> verse event occurring in the course of the use of a drug product in professional practice; an adverse event occurring from drug overdose whether accidental or intentional; an adverse event occurring from drug abuse; an adverse event occurring from drug withdrawal; and any failure of expected pharmacological action.

21 C.F.R. § 314.80(a) (emphasis added). Adverse events can range from minor reactions, such as fevers, rashes, and mild patient discomfort, to severe side effects, including life-threatening complications or death. *See id.*

The FDA collects adverse event reports from several sources. The FDA receives adverse event reports directly from health care professionals such as physicians, pharmacists, and nurses; scientists conducting clinical studies; and members of the public, including patients, family members, and attorneys. *See* FDA, *Reports Received and Reports Entered into AERS by Year* (as of Mar. 31, 2010), at www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm070434.htm (*AERS Statistics*). Additionally, such individuals often choose to contact the drug manufacturer instead of the FDA: a consumer might spontaneously contact the manufacturer by telephone or over the Internet, or a health care professional might inform a manufacturer about adverse events experienced by one or more patients. Large drug manufacturers, including the members of PhRMA and BIO, receive thousands of such reports annually. *See id.*

Manufacturers are required by regulation to disclose adverse events to the FDA upon learning of them. *See* 21 C.F.R. § 314.80 (establishing post-marketing re-

porting of adverse drug experiences for manufacturers); *see also id.* § 600.80 (establishing similar reporting requirements for biologic products). Most adverse drug events are reported by manufacturers to the FDA on a quarterly basis; severe or unexpected adverse drug events must be transmitted to the FDA within fifteen days after the manufacturer learns of the adverse event. *See id.* § 314.80 (detailing periodic reporting requirements for adverse drug experiences); § 600.80 (detailing periodic reporting requirements for biologic products); *see also* Eng, *Drug Safety: It's a Learning Process*, 24 St. John's J. Legal Comment. 159, 176-182 (2009) (describing structure of adverse event reporting system and identifying limitations).

The FDA receives a significant number of adverse event reports every year. In 2009 alone, the FDA received 546,731 adverse event reports from manufacturers of drugs and biologic therapeutics. *See AERS Statistics.* Consumers and health care professionals lodged an additional 34,173 reports directly with the FDA. *Id.*

The FDA makes adverse event reports available to the public, including the investing community, through a variety of means. The FDA regularly releases raw adverse event report data through a database known as the Adverse Event Reporting System (AERS), which is accessible via the FDA's website and is designed to assist the FDA's post-marketing safety surveillance program for all approved drug and therapeutic biologic products. *See* FDA, *Adverse Event Reporting System*, at www.fda.gov/Drugs/GuidanceComplianceRegulatory Information/Surveillance/AdverseDrugEffects/default.htm (last updated Aug. 20, 2009) (*AERS Database*). Information about certain post-market drugs is also available to the public through the FDA's Safety Information and Adverse Event Reporting Program, commonly

known as MedWatch. *See* FDA, *MedWatch: The FDA Safety Information and Adverse Event Reporting Program*, www.fda.gov/Safety/MedWatch/default.htm (last updated Aug. 25, 2010). The FDA also separately provides lists of any potential signals of serious risks or new safety information that it detects through its review of AERS. FDA, *Potential Signals of Serious Risks/New Safety Information Identified from the Adverse Event Reporting System*, at www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm082196.htm (last updated July 27, 2010) (*AERS Signals*).[2]

Although manufacturers are required to relay each adverse event report they receive to the FDA, medical professionals and patients are under no parallel duty to report adverse events to manufacturers; point-of-care reporting is purely voluntary. Accordingly, a manufacturer may not even learn of adverse event reports associated with its products that are reported directly to the FDA before these reports are published in the AERS database.

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[2] Similarly, the electronic Manufacturer and User Facility Device Experience (MAUDE) database is used to track adverse events associated with approved medical devices and is also available for viewing via the FDA's website. The FDA and the Department of Health and Human Services also track potential adverse reactions to vaccines through the electronic Vaccine Adverse Event Reporting System (VAERS) database. A small number of the adverse event reports received by the FDA are not entered in these databases, usually due to incomplete or missing information. Approximately 15% of the reports received by the FDA were not entered in the AERS database in 2009. *See AERS Statistics*.

Neither a manufacturer nor the FDA can determine the significance of an adverse event report standing alone. Nonetheless, the FDA and drug manufacturers constantly evaluate adverse event reports to determine whether a certain drug can be reasonably suspected of causing a previously unknown side effect. If there is a sufficient indication of a potential safety concern, the FDA may request further epidemiological studies or ask the manufacturer to investigate. Based on an evaluation of the drug's safety profile, the FDA may take significant regulatory action, such as requiring a manufacturer to update a product's labeling information (including warnings and precautions), restricting the use of the drug through a risk management program, communicating new safety information to the public, or, in rare instances, withdrawing the product's FDA approval. *See* 21 U.S.C. §§ 355-1 (risk management programs), 355(o) (labeling changes and postmarketing studies), 355(r) (FDA communication of new safety information), 355(e) (withdrawal of FDA approval); *see also* 42 U.S.C. § 262(j) (applying requirements of Federal Food, Drug, and Cosmetic Act to biologics). Often, however, the FDA finds that there is no connection between the medicine and reported adverse events.[3]

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[3] Adverse event reports may also arise in the context of pre-approval products if a manufacturer becomes aware of adverse events experienced in the clinical trial or testing process. Although the pre-approval context is governed by different FDA regulations and requirements, the same general materiality standard governs for purposes of the securities laws, and the same issues of reliability and causation arise in connection with pre-approval adverse event reports as with post-approval reports. Equally present in the pre-approval context is the concern that the market will react unfavorably to disclosures of adverse events for

B. Adverse Event Reports Frequently Have No Causal Connection To The Product In Question

Importantly for purposes of this case, adverse event reports frequently do not even purport to identify a causal link between the event they report and any given drug product. In fact, as previously discussed, the FDA's definition of an adverse event includes events "associated with the use of a drug in humans, *whether or not considered drug related.*" 21 C.F.R. § 314.80(a) (emphasis added).

The FDA recognizes that adverse event reports, many of which are anecdotal, have significant limitations. As the FDA correctly warns those reviewing adverse event reports via its public database, "there is no certainty that the reported event was actually due to the product." *AERS Database.* The FDA's regulations also recognize as much. *See* 21 C.F.R. § 314.80(k) ("A report or information submitted by an applicant ... does not necessarily reflect a conclusion by the applicant or FDA that the report or information constitutes an admission that the drug caused or contributed to an adverse effect"); *id.* § 803.16 ("A report ... and our release of that report or information, is not necessarily an admission that the device, or you or your employees, caused or contributed to the reportable event."). Even where the FDA has detected a "signal" of a potential

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which there is no evidence of a causal relationship to the subject product. *See In re AstraZeneca Sec. Litig.*, 559 F. Supp. 2d 453, 470 (S.D.N.Y 2008) ("[P]articularly in the testing and development stage, the possible beneficial effects of a drug may be accompanied by adverse side effects, and there may be uncertainty as to how the risk-benefit balance ultimately turns out, and how it will be viewed by regulators.").

serious risk, it expressly warns that inclusion of a product on this list "*does not mean* that FDA has identified a causal relationship between the drug and the listed risk" and "emphasize[s] that the listing of a drug ... does not mean that FDA is suggesting that healthcare providers should not prescribe the drug or that patients taking the drug should stop." *AERS Signals* (emphasis added).

These warnings reflect a common-sense recognition that people who use FDA-approved drugs are often seriously ill and suffer adverse events that are frequently not caused by the drug. Many adverse events are the result of an underlying medical condition or something else altogether. Additionally, the amount of publicity that a drug receives may dramatically alter the number of adverse event reports submitted to manufacturers and the FDA. The veracity and accuracy of these reports are also inherently difficult to verify. For these reasons, the FDA cautions that anecdotal adverse event reports "cannot be used to calculate the incidence of an adverse event in the U.S. population." *AERS Database.*

Accordingly, it is not uncommon for the FDA to conclude that, notwithstanding the receipt of adverse event reports, no regulatory action is warranted regarding a particular drug. One example arose earlier this year when the FDA examined several adverse event reports for the drug Spiriva®, a drug co-marketed by Pfizer Inc. and Boehringer Ingelheim Pharmaceuticals, Inc., members of PhRMA and BIO. Spiriva treats breathing problems associated with chronic obstructive pulmonary disease. Certain adverse event reports correlated use of Spiriva with a possible increased risk of cardiovascular problems. The FDA concluded that the available data did not support an association between

the use of the drug and an increased risk for these serious cardiovascular events. *See* FDA, *Tiotropium (marketed as Spiriva HandiHaler)*, at www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm095076.htm (last updated Jan. 14, 2010).

As this example illustrates, the mere presence of adverse event reports, standing alone, without any scientific analysis, does not permit a logical inference that the reported events were caused by the subject drug. Adverse event reports may be mistaken, fabricated, or incomplete, and they also may identify a factual coincidence and not a causal relationship. At most, they are a prompt to further investigation and analysis. Moreover, the mere presence of adverse event reports is by no means an unusual occurrence. The broad definition of "adverse event" and the relative costlessness of providing a report to the FDA or a manufacturer ensures that virtually every drug will be the subject of numerous such reports, even where there is no scientific basis to believe that the drug caused the adverse event.

C. Statistically Insignificant Adverse Event Reports, Standing Alone, Are Immaterial Because They Do Not Threaten A Drug's Sales Or Profitability

Because adverse event reports take many forms and frequently offer no meaningful information about the drug in question, neither the FDA nor a manufacturer can or should base rational decisions on such reports without first determining whether they are statistically significant, *i.e.* "that the ill effects may be caused by—rather than randomly associated with—use of the drugs." *In re Carter-Wallace, Inc. Sec. Litig.*, 150 F.3d 153, 157 (2d Cir. 1998) ("*Carter-Wallace I*").

More often than not, adverse event reports do not lead to any formal FDA regulatory action such as a label change, a so-called "black box" warning advising that the drug may have serious side effects, or a recall. The few that do ultimately trigger such a regulatory response do so only after careful review by the FDA. Therefore, a drug's sales and profitability are likely to be altered only after concrete, scientific analysis takes place, and only at that point would such information (without more) potentially be "material" to a reasonable investor.

An omission is material when there is a "substantial likelihood that the disclosure of the omitted fact would have been viewed by the *reasonable investor* as having *significantly altered* the total mix of information made available." *Basic Inc.* v. *Levinson*, 485 U.S. 224, 231-232 (1988) (emphasis added, internal quotation marks omitted). But statistically insignificant adverse event reports are the normal state of affairs for marketed drug products, given the ease with which such reports can be made and the FDA's regulatory *requirement* that manufacturers disclose them regardless of causation. 21 C.F.R. § 314.80(a). Statistically insignificant reports do not alter, much less "significantly" alter, the total mix of information available to the investing public. Indeed, "[s]ome adverse events may be expected to occur randomly, especially with a drug designed to treat people that are already ill." *In re Carter-Wallace, Inc. Sec. Litig.*, 220 F.3d 36, 41 (2d Cir. 2000) ("*Carter-Wallace II*").

Courts have accordingly ruled that "the receipt of an adverse report does not in and of itself show a causal relationship between [a drug] and the illness mentioned in the report." *Carter-Wallace II*, 220 F.3d at 41. And where there is no scientifically reliable allegation of a

causal connection, there is *a fortiori* no materiality. Thus, in the absence of such statistically significant information, manufacturers are under no obligation to address such reports in their securities filings.

A securities plaintiff might state a claim by plausibly alleging (among other elements) that a company intentionally failed to disclose adverse event reports that a reliable source—such as the FDA, the company's own internal safety professionals, or a clinical study committee—had concluded were statistically significant, because such a conclusion would be likely to harm a drug's future sales. But it is only when reported adverse events rise to that level of statistical significance—thus permitting a *sound* inference of causation between drug and event—that such reports, without more, could become material for purposes of the securities laws.[4]

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[4] Moreover, although alleging statistical significance is necessary for a plaintiff to plead a securities fraud claim based solely on undisclosed adverse event reports, such an allegation is not sufficient to survive a motion to dismiss where it is unsupportable or the plaintiff's theory is implausible. Thus, it would not be sufficient for a plaintiff to assert, in a conclusory fashion and without supporting factual allegations, that certain adverse event reports were statistically significant. *See Ashcroft* v. *Iqbal*, 129 S. Ct. 1937, 1949 (2009) (to survive a motion to dismiss, the complaint must have "facial plausibility," *i.e.*, "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged"); *Bell Atl. Corp.* v. *Twombly*, 550 U.S. 544, 570 (2007) (complaint must "state a claim to relief that is plausible on its face"); *Oran* v. *Stafford*, 226 F.3d 275, 284 (3d Cir. 2000) (Alito, J.) (requiring that the allegedly withheld data be able to "demonstrate[] a[] medically conclusive link in light of the millions of prescriptions written" for the drug in question); *see also New Jersey Carpenters Pension & Annuity Funds* v. *Biogen IDEC Inc.*, 537 F.3d 35, 49-50 (1st Cir. 2008) (allegations must provide a

This approach is all the more sensible given that most adverse event data are already made available to the public by the FDA through its MedWatch system, the AERS database, and other FDA sources, data of which investors are presumed to be aware. *See In re Zyprexa Prods. Liab. Litig.*, 549 F. Supp. 2d 496, 534 (E.D.N.Y. 2008) (investors are presumed to know about "available medical research, media coverage ... and securities analyst reports"); *Yanek* v. *Staar Surgical Co.*, 388 F. Supp. 2d 1110, 1126 (C.D. Cal. 2005) ("both the information about the recalls and the MAUDE printouts were available through the FDA and thus were publicly known or available information"). A requirement that manufacturers report adverse event information not only to the FDA but also in a company's SEC filings would therefore be redundant and unduly burdensome. And, as this Court has frequently noted, the "market price of shares traded on well-developed markets reflects all publicly available information." *Basic*, 485 U.S. at 246.[5]

"basis to conclude" that "the[] results ... were statistically significant").

[5] The fact that raw adverse event information is publicly available also calls into question whether a plaintiff making claims like Respondents' claim here could plead or prove loss causation, because the allegedly material information was already available to the public. Loss causation is a separate element of a Rule 10b-5 claim that requires plaintiffs to show "a causal connection between the material misrepresentation and the loss." *Dura Pharm., Inc.* v. *Broudo*, 544 U.S. 336, 342 (2005). To establish this connection, plaintiffs must show that a previously hidden truth is revealed through a disclosure that corrects a prior statement. *Id.* This "corrective disclosure" must at least reveal to the market that the prior representation was false. *Lentell* v. *Merrill Lynch & Co.*, 396 F.3d 161, 175 n.4 (2d Cir. 2005). In scenarios involving adverse

Some courts have incorrectly questioned this concept, suggesting that the market could be misled by a manufacturer's failure to disclose in a securities filing information that was already in the market by virtue of the company's FDA submissions. *See In re Pfizer Inc. Sec. Litig.*, 584 F. Supp. 2d 621, 636-637 (S.D.N.Y. 2008) (disagreeing with the "presum[ption] that disclosure to the FDA is equivalent to disclosure to the market" even though "it is likely the FDA would highlight or require disclosure of material negative safety information about a drug"). This Court has made clear that this is not how the efficient market functions. *Basic*, 485 U.S. at 247 ("publicly available information is reflected in market price"). The market is presumed to have assimilated information that is in the public domain; this would certainly include information available through a searchable government database such as AERS, in published medical journals, or in the news media. Indeed, it would seem incongruous to allow plaintiffs to claim, on the one hand, that they relied on information in the market (positive statements made by a publicly traded company about its drugs) while simultaneously disavowing knowledge of other readily available information (the adverse event report data made available by the FDA).

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event reports, however, the information contained in a manufacturer's disclosure to the SEC of material adverse event reports will merely confirm information previously disclosed to the FDA, and a plaintiff will have a difficult time establishing loss causation. *See In re Retek Inc. Sec. Litig.*, 621 F. Supp. 2d 690, 705 (D. Minn. 2009) ("[C]onfirmatory information—that information already known to the market—may not constitute such a corrective disclosure" (internal quotation marks omitted)).

In the *Carter-Wallace* cases, a company withdrew its product (an epilepsy drug) from the market when it concluded the drug was causing deaths. The Second Circuit upheld the dismissal of securities fraud claims notwithstanding numerous earlier adverse event reports, because

> [d]rug companies need not disclose isolated reports of illnesses suffered by users of their drugs until those reports provide statistically significant evidence that the ill effects may be caused by—rather than randomly associated with—use of the drugs and are sufficiently serious and frequent to affect future earnings.

Carter-Wallace I, 150 F.3d at 157. Absent such evidence, the company's projections of increased sales were not materially misleading. *Id.*; *see also Carter-Wallace II*, 220 F.3d at 40 (rejecting allegations of fraud even though plaintiffs alleged that the adverse reports were "extremely serious" and the "number of incidents was ... statistically unacceptable").

Similarly, in *Oran* v. *Stafford*, 226 F.3d 275 (3d Cir. 2000) (Alito, J.), the Third Circuit rejected securities fraud claims based on the nondisclosure of adverse patient data concerning a combination of diet drugs, including 55 reports of heart-valve disorders in patients taking the drugs and a report by the Mayo Clinic raising "significant concern that this combination ... has important implications regarding valvular disease." *Id.* at 279-280, 282 (internal quotation marks omitted). The Third Circuit held that "[b]ecause the link between the ... drugs and heart-valve disorders was never definitively established during the relevant period ... [defendant's] failure to disclose this data cannot render its statements about the inconclusiveness of the relation-

ship materially misleading." *Id.* at 284. The court also reasoned that, in the absence of statistically significant data establishing a link between the drugs and the adverse events, it was speculative whether the company would be exposed to significant product liability claims, and there was no duty to disclose information concerning the extent of any such claims. *Id.* at 285-286.

Likewise, in the recent decision of *In re Medtronic Inc., Securities Litigation*, a district court dismissed a securities fraud claim based on a failure to disclose statistically insignificant adverse event information where a physician informed the defendant that adverse events might indicate a potential safety issue with a particular product, after which the defendant commissioned a broader study. 618 F. Supp. 2d 1016, 1026, 1030 (D. Minn. 2009), *appeal pending, Detroit Gen. Ret. System* v. *Medtronic, Inc.* (8th Cir. No. 09-2518). The company concluded that the adverse events were not statistically significant but might become so later, decided to suspend distribution of the product voluntarily, and announced this decision promptly to the public and the market. In a securities class action suit similar to the one at issue here, the district court concluded that the company's handling of this situation was entirely appropriate and dismissed the plaintiffs' complaint because no *rational* investor would have believed that the statistically insignificant reports about the product would have had any effect on the company's stock price. 618 F. Supp. 2d at 1026 ("failure to disclose additional statistically insignificant information cannot have been materially misleading").[6]

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[6] *See also, e.g., In re Elan Corp. Sec. Litig.*, 543 F. Supp. 2d 187, 213 (S.D.N.Y. 2008) ("Even if scientists suspected that [the

In *New Jersey Carpenters Pension & Annuity Funds* v. *Biogen IDEC Inc.*, 537 F.3d 35 (1st Cir. 2008), the First Circuit adopted the statistical significance test of *Carter-Wallace* and *Oran* in the different but related context of scienter. The First Circuit ruled that "[a] statement cannot be intentionally misleading if the defendant did not have sufficient information at the relevant time to form an evaluation that there was a need to disclose certain information and to form an intent not to disclose it." *Id.* at 45. In other words, a manufacturer cannot intentionally or recklessly mislead the markets by failing to disclose statistically insignificant adverse event reports, because the manufacturer can reasonably believe such information to be immaterial. Accordingly, mere awareness of statistically-insignificant reports cannot give rise to a cogent inference of scienter. *Tellabs, Inc.* v. *Makor Issues & Rights, Ltd.*, 551 U.S. 308 (2007); *see also Biogen*, 537 F.3d at 50 ("There is no plausible inference from the reports of just five [adverse events] that the defendants knew of any causal relationship between the use of [the drug] and the [adverse events], and then intentionally withheld data."); *Carter-Wallace II*, 220 F.3d at 41 (the absence of a material omission itself negates any

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drug at issue] might cause adverse events and Defendants knew of these suspicions, these facts would not have required Defendants to conclude that these effects were real before such a relationship was established using accepted statistical methods and standards of proof."); *In re Bayer AG Sec. Litig.*, No. 03-1546, 2004 WL 2190357, at *4 (S.D.N.Y. Sept. 30, 2004) (even though the company was "inundat[ed]" with increasing numbers of adverse event reports, it had no duty to disclose them prior to a meeting of its safety executives where a "consensus ... emerged" that the data concerning the drug's dangers was "putting the brand at risk" (internal quotation marks omitted)).

finding of scienter, because it cannot be willful or reckless not to disclose immaterial adverse event reports).[7]

Contrary to the Ninth Circuit's reasoning, the use of statistical significance in this context does not run afoul of this Court's caution regarding "bright-line rule[s]." *Basic*, 485 U.S. at 236. This Court did not reject general principles that could be used to determine materiality, and it certainly did not hold that a dispute regarding materiality must always survive a motion to dismiss. Rather, the Court warned against treating "ease of application alone" as "an excuse for ignoring the purposes of the Securities Acts and Congress' policy decisions," noting that an approach that "designates a single fact or occurrence as *always determinative* of an inherently fact-specific finding such as materiality, must necessarily be overinclusive or underinclusive." *Id.* (emphasis added).

But nothing in the *Carter-Wallace* cases, *Oran*, or the numerous other decisions that take a similar approach suggests that statistical significance is *always*

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[7] *See also, e.g.*, *Elan*, 543 F. Supp. 2d at 218 (failure to allege that "Defendants knew of any statistically significant or causal relationship" between drug and adverse effect undercut plaintiffs' allegations of scienter); *In re Bausch & Lomb, Inc. Sec. Litig.*, 592 F. Supp. 2d 328, 350 (W.D.N.Y. 2008) (dismissing complaint for failure to plead scienter where plaintiffs failed to allege that "anyone at [defendant company] believed during the Class Period that there was a causal link between [product] and [adverse event], much less that [the company] had reached an internal consensus at odds with its public statements concerning [product's] safety"); *AstraZeneca*, 559 F. Supp. 2d at 461 (dismissing complaint for failure to plead scienter where pharmaceutical company received adverse medical reports about a pre-market drug but continued to issue positive press releases stating, inter alia, that its drug had a "positive benefit-risk profile")

determinative. *See Elan*, 543 F. Supp. 2d at 210 ("[T]his Court agrees ... that *Carter-Wallace I* does not establish a bright-line rule for the materiality of information regarding drug safety risks."). On the contrary, it is possible that, in certain limited circumstances, statistically insignificant adverse event reports may arise together with *other* information that, when viewed as a whole, establishes that drug sales are threatened and a drop in sales of the drug would have a material effect on the manufacturer's future earnings. *See, e.g.*, *Medtronic*, 618 F. Supp. 2d at 1026 (considering possible "other indications" of materiality beyond statistical significance but finding that none "demonstrat[ed] that the undisclosed information was a sufficiently serious threat to Medtronic's future earnings so as to require disclosure"); *Bausch & Lomb*, 592 F. Supp. 2d at 350 (statistically insignificant information could "become material even in the absence of statistically significant evidence in light of other indications that the risk associated with adverse drug events is legitimate and serious enough to threaten drug sales"); *Bayer*, 2004 WL 2190357, at *9-10 (adverse event reports lacking statistical significance, when considered in conjunction with an internal corporate "consensus" that a drug's "potential dangers were putting the brand at risk," were enough to find materiality; adverse event reports, "coupled with other evidence," can demonstrate that "defendants viewed the adverse event reports as sufficiently serious and frequent to affect future earnings").

In this case, the Ninth Circuit did not rely on any allegations of additional indications of materiality. Rather, it denied the motion to dismiss because the presence of adverse event reports *alone*—with no allegation of statistical significance or *any other* contextual information suggesting causation—could, in the court's

view, be found to have significantly altered the total mix of information available to a reasonable investor.[8] That was error—not because the court failed to apply a "bright-line rule," but because it failed to recognize that the mere allegation of undisclosed adverse event reports was insufficient to allege a material omission.[9]

Further, even once reported adverse events are found to be statistically significant, it does not necessarily follow that these events are "material" for purposes of the securities laws. The underlying reporting may be inaccurate, or the nature of the adverse events may be too minor to have any effect on the drug's commercial success. The affected drug must also be suffi-

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[8] Even the case upon which the Ninth Circuit most heavily relied, *In re Pfizer Inc. Securities Litigation*, recognized that the standard for pleading the materiality of adverse events is based on statistical significance. 584 F. Supp. 2d at 633. However, the district court in *Pfizer* nonetheless denied the defendants' motion to dismiss, concluding that it could not ascertain on the pleadings or by judicial notice whether two clinical studies cited in the complaint demonstrated a statistically significant link between two of Pfizer's prescription pain medications and cardiovascular events, even though the FDA had determined that the studies showed no such link. The *Pfizer* court concluded that "statistical significance is a question of fact." *Id.* at 635-636. That decision was erroneous because plaintiffs had the burden of pleading that, at the time of the alleged nondisclosures and misstatements, the studies at issue demonstrated a statistically significant causal link between the drugs and the adverse cardiovascular events, and the court failed to address whether plaintiffs met their burden.

[9] PhRMA and BIO take no position on whether Respondents *could* allege sufficient additional facts to permit a reasonable jury to conclude that the adverse event reports on which they rely were material. Under the Ninth Circuit's ruling, Respondents were not required to make such an allegation; that is in itself sufficient grounds to reverse in this case.

ciently profitable and represent a significant enough portion of the company's earnings or future products that a drop in sales would have a material effect on the manufacturer's overall financial position. *See Carter-Wallace I*, 150 F.3d at 157 (statistically significant adverse events must be "sufficiently serious and frequent to affect future earnings"); *Medtronic*, 618 F. Supp. 2d at 1030 ("[T]here is nothing to suggest that such undisclosed information constituted a sufficiently serious threat to Medtronic's stock price as to render such information material."); *see also Parnes* v. *Gateway 2000, Inc.*, 122 F.3d 539, 547 (8th Cir. 1997) (statements or omissions are not material where they "present or conceal such insignificant data that ... [they] simply would not matter to a reasonable investor").

II. The Judgment Below Would Effectively Require Manufacturers To Flood The Markets With Disclosures Of Adverse Event Reports, To The Detriment Of Investors And Patients

The Ninth Circuit's ruling has an additional flaw: if allowed to stand, it would require a company to disclose in its securities filings statistically insignificant adverse event reports, which would in effect require it to disclose adverse event reports for all products. This would result in the inclusion of literally thousands of such reports per year in biopharmaceutical companies' securities filings. *See AERS Statistics*. The Ninth Circuit's ruling would require biopharmaceutical companies to "report on every conjecture, rumor or adverse claim," an outcome that would "unnecessarily burden the industry." *In re Carter-Wallace, Inc. Sec. Litig.*, No 94-5704, 1999 WL 1029713, at *1 (S.D.N.Y. Nov. 10, 1999), *aff'd*, 220 F.3d 36 (2d Cir. 2000). Nor does the Ninth Circuit "clearly explain how the accumulation of additional anecdotal data, short of statistical signifi-

cance," adds anything to the disclosures already made to the investing public by biopharmaceutical manufacturers. *Oran*, 226 F.3d at 284. Such a disclosure regime contravenes this Court's command that issuers not "bury the shareholders in an avalanche of trivial information." *TSC Indus. Inc.* v. *Northway, Inc.*, 426 U.S. 438, 448 (1976).[10]

The decision below also disregards this Court's admonition that plaintiffs "with a largely groundless claim" should not be able "to simply take up the time of a number of other people, with the right to do so representing an *in terrorem* increment of the settlement value, rather than a reasonably founded hope that the [discovery] process will reveal relevant evidence." *Dura Pharm., Inc.* v. *Broudo*, 544 U.S. 336, 347 (2005) (quoting *Blue Chip Stamps* v. *Manor Drug Stores*, 421 U.S. 723, 730, 741 (1975)). Plaintiffs should not be permitted to file a securities fraud suit "with only a faint

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[10] The disclosure rule contemplated by the Ninth Circuit would effectively require companies to address every adverse event report in a quarterly SEC filing to fend off securities claims for failure to disclose. As one court has observed, this potential for overly broad disclosure could expose manufacturers to securities fraud claims for making "misleading" *over*-disclosures. *See In re Medimmune, Inc. Sec. Litig.*, 873 F. Supp. 953, 966 (D. Md. 1995) (noting that premature disclosure without statistical significance could "cause ... stock to decline in value [and then] rise ... again"). Under this theory, if a company discloses an isolated adverse event report as "material," and the report later proves to have been specious, the report's disclosure would needlessly drive down the stock price. Investors might then claim to have been misled by this over-disclosure, exposing the company to securities lawsuits in both directions. *Id.* The securities laws should not be construed to expose publicly-traded companies to lawsuits every time their share price dips.

hope" that the expensive and time-consuming discovery process might ultimately reveal some plausible evidence of materiality. *Id.* (citation omitted). At the very least, plaintiffs seeking to base their allegation of causation solely on undisclosed adverse event reports should be required to plead specific facts that, if proven, would show that those reports were statistically significant.[11]

The approach followed by the First, Second, and Third Circuits, by contrast, prevents plaintiffs from forcing manufacturers into expensive and time-consuming discovery on the strength of anecdotal reports that permit no plausible inference of materiality.

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[11] Indeed, the *Pfizer* securities litigation reveals the danger of allowing plaintiffs to pass the motion to dismiss stage without pleading that, at the time of the alleged nondisclosure or misstatement, there was statistically significant evidence linking a drug to adverse events. Since the motion to dismiss was denied in that case—and the mandatory stay of discovery under the Private Securities Litigation Reform Act lapsed—900 hours of deposition testimony have been ordered, millions of pages of documents have been produced, and the parties have engaged in costly expert discovery that culminated in a full *Daubert* hearing. *See In re Pfizer Inc. Sec. Litig.*, No. 04-9866, 2010 WL 1047618 (S.D.N.Y. Mar. 22, 2010). At the time of the alleged nondisclosures, both of the drugs at issue had been extensively tested on thousands of patients in studies conducted before and after they went on the market, and these studies showed no statistically significant link between the drugs and the adverse cardiovascular events. Despite this extensive testing—and the FDA's decision to take no action after receiving its results, which the FDA found did not demonstrate a statistically significant link between the drugs and the adverse events—Pfizer has been forced to expend millions of dollars to conduct discovery and defend the litigation. These substantial costs are borne directly by the company and its shareholders and indirectly by Pfizer's patients.

That approach is not an additional rule; it simply implements Congress's practical and necessary judgment that nondisclosure of immaterial information should not ground potentially abusive securities litigation. *See Dura*, 544 U.S. at 345 (noting that the securities laws are not "broad insurance against market losses").

The Ninth Circuit's rule would also effectively require manufacturers to disclose to the investing public information that the FDA and manufacturers have concluded does not warrant a warning to patients or health care professionals (apart from making the raw information publicly available via the FDA's website). Essentially, the Ninth Circuit's interpretation of the securities laws would require manufacturers to place an imprimatur of legitimacy on every adverse event anecdote received, effectively characterizing these reports as material through their disclosure—irrespective of reliability or verifiability—even though federal and state public health laws deem it immaterial for patients using the treatment or health care professionals prescribing it. But over-disclosure is disfavored in the public health context for good reason: it can lead patients and health care professionals to avoid or discontinue using beneficial, perhaps life-saving, treatments.

A paradigmatic example of the risk of over-disclosure arose with respect to implantable cardiac defibrillators—medical devices that are implanted in patients at risk of sudden cardiac death due to heart rhythm abnormalities. In 2004 and 2005, several defibrillator manufacturers reported a potential short-circuiting defect to the FDA. The potential defect was rare and appeared only under certain specific conditions. Nonetheless, after media coverage of a specific adverse event, the manufacturers issued advisories to health care professionals. As a result of the ensuing

publicity, many patients elected to replace their implanted devices. A scientific study later concluded that the elective replacements were in fact riskier than the potential defect. Gould & Krahn, *Complications Associated with Implantable Cardioverter-Defibrillator Replacement in Response to Device Advisories*, 295 J. Am. Med. Ass'n 1907, 1907-1911 (2006) (describing a study of patient outcomes from replacement surgery in response to device advisories); *see also* von Biela, *A Disclosure Dilemma: What You Don't Know Can Kill You, But So Can What You Do Know*, 65 Food & Drug L. J. 317 (2010) (describing various situations in which adverse event reports with no proven causal connection to the treatment in question led to over-warning by FDA and manufacturers, with results detrimental to public health). The Ninth Circuit's rule will only increase the frequency of such harmful and unnecessary reactions.

CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted.

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AMICUS CURIAE BRIEF

No. 09-1156

In The Supreme Court of the United States

MATRIXX INITIATIVES INC., *et al.*,

Petitioners,

v.

JAMES SIRACUSANO, *et al.*,

Respondents.

On Writ Of Certiorari To The United States Court Of Appeals For The Ninth Circuit

BRIEF FOR PROFESSORS AT LAW AND BUSINESS SCHOOLS AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENTS

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QUESTION PRESENTED

Will the application of a test of statistical significance to adverse event reports for widely distributed drugs result in a bright-line test for materiality of a kind that is inconsistent with the analytical framework set out in *TSC Indus. v. Northway*, 426 U.S. 438 (1976) and *Basic v. Levinson,* 485 U.S. 224 (1988)?

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INTEREST OF *AMICI CURIAE*[1]

Amici are scholars at American law and business schools whose research and teaching focus on federal securities regulation and the governance of public corporations.[2] Many have written on the antifraud provisions under the federal securities laws and some were cited in *Basic v. Levinson*, 485 U.S. 224 (1988), a seminal case on the subject.[3]

Amici have no financial stake in the outcome of this litigation but are interested in ensuring an accurate interpretation of the standard for materiality under the antifraud provisions of the federal

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[1] This brief was not authored, in whole or in part, by counsel for either party, and no person other than *amici* and their academic institutions contributed monetarily to the preparation or submission of this brief. This amicus brief is filed pursuant to the blanket consent executed by both parties and filed with this Court (by Respondents on July 28, 2010 and by Petitioner on July 30, 2010).

[2] The authors on the cover of this brief also drafted an amicus brief filed in *Merck & Co. v. Reynolds*, 130 S. Ct. 1784 (2010). *See Brief of Amici Curiae Faculty at Law and Business Schools in Support of Respondents, Merck & Co. v. Reynolds*, No. 08-905, Oct. 26, 2009.

[3] *See Basic*, 485 U.S., at 235 n.12 (*citing* Brown, *Corporate Secrecy, the Federal Securities Laws, and the Disclosure of Ongoing Negotiations*, 36 CATH. U. L. REV. 93, 145-155 (1986)); *Id.* at 246 n.24 (*citing* Dennis, *Materiality and the Efficient Capital Market Model: A Recipe for the Total Mix*, 25 WM. & MARY L. REV. 373, 374-381, and n.1 (1984)); *Id.* at 247 n.26 & 256 (*citing* Black, *Fraud on the Market: A Criticism of Dispensing with Reliance, Requirements in Certain Open Market Transactions*, 62 N.C. L. REV. 435 (1984)).

securities laws. It is the view of those on this brief that the application of a test of statistical significance to adverse event reports will result in a bright-line test for materiality that is inconsistent with the analytical framework first set out in *TSC Indus. v. Northway*, 426 U.S. 438 (1976) and directly contradicts this Court's reasoning in *Basic*.[4]

SUMMARY OF ARGUMENT

This case seeks a *sub silentio* reversal of *Basic* and the imposition of a test that is fundamentally inconsistent with the reasoning in *Northway*.

Petitioners challenge the materiality of quantitative data that allegedly shows an association between Zicam Cold Remedy ("Zicam") and anosmia, the loss of smell. They argue for a bright-line test that requires proof of "statistical significance" as a precondition for any determination of materiality. Under the proposed formulation, plaintiffs would need to "at least plead facts establishing that the rate of reported adverse incidents among product users exceeded the relevant background rate by a statistically significant degree." *Brief for Petitioners*, *Matrixx Initiatives, Inc. v. Siracusano* (No. 09-1156), at 33. The

[4] In addition to those scholars listed on the front page of the brief, a full list of *amici*, who joined this brief as individuals and not representatives of any institutions with which they are affiliated, is set forth in the Appendix.

approach conflicts with the analytical framework for materiality set out by this Court in *Northway* and directly contradicts the reasoning in *Basic*.

Petitioners seek to avoid this conflict by disclaiming the bright-line nature of the test and asserting that it does not artificially exclude information but merely "*defines* the information a reasonable investor would consider relevant. . . ." Pet. Br. 43. The attempted distinction is unavailing. As with the agreement-in-principle test rejected by this Court in *Basic*, Petitioner's formulation would result in the imposition of an underinclusive test that arbitrarily excludes information important to reasonable investors.

Petitioners do not and cannot establish that investors will only find reports important upon a showing of a statistical significance. Moreover, the approach is inconsistent with assumptions underlying this Court's use of a "total mix" analysis. Statistical significance assumes away, at least in the first instance, any contextual examination of the available information and presupposes that the market singularly relies on the presence or absence of a mathematically validated association between the drug and the adverse events at issue. The approach treats investors – whether analysts, institutional owners, or market professionals – as "nitwits unable to appreciate" the importance of any other information that could affect investment decisions. *Basic*, 485 U.S. at 234 (*quoting Flamm v. Eberstadt,* 814 F.2d 1169, 1175 (7th Cir.), *cert. denied*, 484 U.S. 853 (1987)).

Even if investors can be said to require evidence of an association between a drug and adverse health effect, statistical significance is not the only method of establishing the requisite relationship. The quantitative approach proposed by Petitioners does not take into account reports from scientifically valid studies that, while not statistically significant, nonetheless provide evidence of biological significance. The test also would render immaterial reports arising out of, or supported by, observational studies that, while not statistically significant, nonetheless represent reliable methods of demonstrating an association between the drug's administration and serious health effects. Indeed, not even the Food and Drug Administration ("FDA") or manufacturers will always wait for statistical significance before taking action with respect to drug safety.

Nor has the case been made that there is a need for a bright-line test in these circumstances. *Northway* created the analytical template for addressing the materiality of factual misstatements or omissions under the antifraud provisions of the federal securities laws. Information is material if there is a substantial likelihood it would be important to a reasonable investor in making an investment decision or if there is a substantial likelihood that the information would, if disclosed, significantly impact the total mix of available information. The test is fact specific and eschews reliance on bright-line tests.

The materiality standard first set forth in *Northway* has proved sufficiently robust to allow courts to resolve the materiality of quantitative thresholds such as misstatements in earnings or the number of adverse event reports. Quantitative information is typically only a starting point for the analysis of materiality and must be considered in light of all other factors that could render the extant information important to reasonable investors. The Securities and Exchange Commission has likewise rejected numerical cut offs and bright-line tests and instructed that the analysis take into consideration "all the relevant circumstances. . . ." *See* SEC Staff Accounting Bulletin No. 99 (August 12, 1999). Courts have successfully used this approach in resolving the materiality of adverse event reports.

A fact intensive analysis does not impose an unfair burden on manufacturers and will not result in excessive, unfiltered disclosure to investors. *Northway* resolved the concern over an "avalanche of trivial information" by rejecting an approach to materiality that encompassed what "might" be important to a reasonable investor in favor of a "would" and "actual significance" standard. The standard does not, therefore, impose on manufacturers an obligation to disclose all adverse effect reports. In many instances, the reports will be immaterial, either because the health effects are not serious, earnings from the drug are not material, or the reports have no other significance and are merely cumulative.

Rejection of the test of statistical significance will also not provide manufacturers with "a strong incentive simply to disclose all" reports. Pet. Br. 29. Lower courts already routinely apply the *Northway* standard in determining the materiality of adverse event reports. This has not resulted in manufacturers making all such reports available to the public. Reaffirming the longstanding standard set out in *Northway* will leave the law unaltered and not necessitate any change in existing disclosure practices by manufacturers.

Likewise, even if voluntary disclosure of adverse event reports does occur, the case has not been made that this will harm investors. *Northway* did recognize that excessive disclosure could, in some instances, interfere with informed decision making. *See* 426 U.S. at 448-49. But the concern arose in the context of a proxy solicitation. In those circumstances, shareholders are asked to make an informed decision based upon the information included within the materials distributed to them by the company. Including excessive amounts of unrelated information within the proxy materials could make the decision making process more difficult.

This case, however, involves disclosure to the market, not to shareholders. Market disclosure typically occurs through press releases, SEC filings, or postings on the Internet. The information is not sent directly to shareholders but is available to, and filtered by, analysts and other market professionals who have an economic incentive to accurately reflect

the information in share prices. Any safety data revealed by manufacturers will undergo the same filtering process, presumably improving the efficiency of share prices. Consistent with this approach, Congress has encouraged the Securities and Exchange Commission to develop a system of real-time disclosure for public companies.

In any event, the possibility of harm resulting from disclosure is not, as *Basic* reminds, appropriately resolved under the rubric of materiality. This concern is better addressed in the context of the duty to disclose. As this Court has noted often, silence absent a duty to disclose does not violate the antifraud provisions.

The traditional fact intensive approach set out in *Northway* and reiterated in *Basic* provides an appropriate framework for resolving the materiality issue in this case. The FDA and courts have relied on a number of factors in resolving drug safety issues, many present here.

The Complaint contains allegations of reports from health care professionals and lawyers (in the form of lawsuits) received by Matrixx Initiatives Inc. ("Matrixx" or the "Company") of patients suffering from anosmia after the use of Zicam.

The reports of Zicam's potential threat to health, however, represent only a starting point in assessing the importance of the information to reasonable investors. Other factors that require consideration include: (1) the "rare" nature of the condition; (2) temporal

connections between Zicam and the loss of smell; (3) the fact that, as an over-the-counter homeopathic drug, Zicam was not required to undergo the same rigorous testing required for new drugs approved by the FDA and did not, therefore, have a safety profile approved by the FDA; (4) the existence of scientific studies that link zinc to a loss of smell; (5) the sources of the reports, particularly those submitted by professionals from the University of Colorado Health Sciences Center; (6) awareness of research conducted by health care professionals from the University of Colorado Health Sciences Center raising concerns about the association between Zicam and loss of smell; (7) the response by Matrixx to the reports, including, in 2002, the retention of a consultant to review the product and consideration of animal testing and, in 2004, the convocation of a two-day conference "of physicians and scientists to review current information on smell disorders," Compl. ¶45; and (8) a decline in share prices when an article appeared in the Dow Jones Newswire on Jan. 30, 2004, reporting that the FDA was looking into complaints that "an over-the-counter common-cold medicine manufactured by" Matrixx may cause "some users to lose their sense of smell," Compl., at ¶¶40, 41, and again following a report on Feb. 6, 2004, on *Good Morning America*, about "the connection between Matrixx's zinc gluconate and anosmia." Compl., at ¶¶42, 43.

To impose a requirement that reports must be statistically significant overlooks the central question

in determining materiality: whether it is substantially likely that a reasonable investor would consider the omitted or misstated facts to have significantly altered the total mix of available information. The information need not have produced a different outcome but only have assumed "actual significance" in the deliberative process. The analysis is, as *Northway* rightfully recognized, a subtle one that requires a "delicate assessment of the inferences" in the context of all factors that could render the information important to a reasonable investor. This cannot be done through resort to a single test or factor. It is a standard that has functioned effectively for more than three decades.

To the extent that there is a need for clarity in this area, the matter is better left to the SEC, where the complexities attendant with the adoption of a materiality standard incorporating statistical significance can better be addressed. At least in the first instance, administrative agencies have the expertise to frame the salient issues and clarify the standards for interpreting the statutes that Congress has charged them to enforce. Indeed, here, the administrative agency promulgated the regulation that is the subject of the parties' dispute, Rule 10b-5. 17 C.F.R. § 240.10b-5.

ARGUMENT

I. The Use of Statistical Significance as a Bright-line Test for Determining Materiality Is Inconsistent with the Analytical Framework Set Out By This Court in *Northway* and Conflicts with the Reasoning in *Basic*

This Court developed the standard for materiality under the federal securities laws in two seminal cases, *Northway* and *Basic*. *Northway*, a case brought under the proxy rules, set out the common formula. Information is material if there is a substantial likelihood it would be important to a reasonable investor in making an investment decision or if there is "a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available." *Northway*, 426 U.S. at 449. *Northway* emphasized the fact intensive and subtle nature of the analysis. *Id.* at 450 (determination requires "delicate assessments of the inferences" that are to be drawn "from a given set of facts").

More than a decade later, this Court in *Basic* reiterated the fact intensive formulation and extended the approach to actions brought under Rule 10b-5. 17 C.F.R. § 240.10b-5. *Basic* considered and rejected the use of a bright-line test for the disclosure of merger negotiations. As the Court reasoned, "[a]ny approach that designates a single fact or occurrence as always determinative of an inherently fact-specific

finding such as materiality, must necessarily be over- or underinclusive." *Basic*, 485 U.S. at 236.

Efforts to impose a bright-line test of statistical significance in this case raise the same concerns addressed in *Basic*. Petitioners would require plaintiffs to "at least plead facts establishing that the rate of reported adverse incidents among product users exceeded the relevant background rate by a statistically significant degree." Pet. Br. 33. Under the proposed formulation, statistical significance is a necessary, but not always sufficient, condition for determining materiality.[5] The approach, therefore, replaces a fact intensive analysis with a "single fact or occurrence" that results in an underinclusive test for determining materiality.

Petitioners seek to avoid the conflict with *Northway* and *Basic* by asserting that statistical significance does not artificially exclude information but instead "*defines* the information a reasonable investor would consider relevant . . . " Pet. Br. 44. Petitioners do not and cannot establish that investors will only find reports important upon a showing of a statistical significance.[6] Moreover, the approach is inconsistent

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[5] Petitioners assert that while necessary, statistical significance may not be sufficient. *See* Pet. Br. 33 n.15.

[6] *See* Stephen M. Bainbridge & G. Mitu Gulati, *How do Judges Maximize? (The Same Way Everybody Else Does — Boundedly): Rules of Thumb in Securities Fraud Opinions*, 51 EMORY L.J. 83, 151 n.115 (2000) ("[T]he claim is that investors do not think that information is material until it is statistically

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with assumptions underlying this Court's use of a "total mix" analysis. Statistical significance assumes away, at least in the first instance, any contextual examination of the available information and presupposes that the market singularly relies on the presence or absence of a mathematically validated association between the drug and the adverse events at issue. The approach treats investors – whether analysts, institutional owners, or market professionals – as "nitwits unable to appreciate" the importance of any other information that could affect investment decisions. *Basic*, 485 U.S. at 234 (*quoting Flamm v. Eberstadt,* 814 F.2d 1169, 1175 (7th Cir.), *cert. denied*, 484 U.S. 853 (1987)).

Even if investors can be said to require evidence of an association between a drug and adverse health effect, statistical significance is not the only method

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significant. Even if this is correct, how do the courts know of this magical relationship between statistical significance and investor interest. . . ."). Courts in other contexts are moving away from, not toward, reliance on statistical significance as a necessary metric when determining, for example, the admissibility of epidemiological studies. *See, e.g., Cook v. Rockwell Int'l Corp.*, 580 F. Supp. 2d 1071, 1102 (D. Colo. 2006) ("there is a considerable dispute in the scientific community about the necessity or even relevance of statistical significance testing to epidemiological studies."). As Judge Posner has noted in criticizing excessive reliance on statistical significance, "[l]itigation generally is not fussy about evidence; much eyewitness and other nonquantitative evidence is subject to significant possibility of error, yet no effort is made to exclude it if it doesn't satisfy some counterpart to the 5 percent significance test." *Kadas v. MCI Systemhouse Corp.*, 255 F.3d 359, 362 (7th Cir. 2001).

of establishing the requisite relationship. The quantitative approach proposed by Petitioners does not take into account reports from scientifically valid studies that, while not statistically significant, nonetheless provide evidence of biological significance.[7] The test also would render immaterial reports arising out of, or supported by, observational studies that, while not statistically significant, nonetheless are reliable methods of demonstrating an association between the drug's administration and serious health effects.[8]

Statistical significance would also impose on investors a standard higher than that used by regulators and manufacturers in resolving drug safety issues. The FDA and manufacturers will not always wait for a statistically significant number of adverse event reports before taking action with respect to drug safety. They may do so, for example, where underreporting makes it difficult if not impossible to determine the number of occurrences in the population of drug

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[7] *See* Erica Beecher-Monas, *The Heuristics of Intellectual Due Process: A Primer for Triers of Science*, 75 N.Y.U. L. REV. 1563, 1603 (2000).

[8] *See Drug Safety: Improvement Needed in FDA's Postmarket Decision-making and Oversight Process*, GAO-06-402, at 7 n.11 (March 2006) ("*Drug Safety*") ("Observational studies can provide information about the association between certain drug exposures and adverse events."); *see also Reference Manual on Scientific Evidence, Second Edition*, Federal Judicial Center, at 359 (studies "with small sample sizes may find a high relative risk but still not be statistically significant.").

users.[9] Thus, in *In re Carter-Wallace, Inc. Sec. Litig.*, 150 F.3d 153 (2d Cir. 1998), Felbatol was taken off the market after the manufacturers learned of ten cases of aplastic anemia. In *New Jersey Carpenters Pension & Annuity Funds v. Biogen IDEC, Inc.*, 537 F.3d 35 (1st Cir. 2008), the manufacturer withdrew Tysabri, a drug designed to treat autoimmune diseases, from the market after learning that two patients in the clinical trials had contracted progressive multifocal leukoencephalopathy.[10]

Requiring statistical significance as a necessary condition for determining materiality will result in the application of a rigid test that ignores all other

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[9] *See The Adequacy of FDA to Assure the Safety of the Drug Supply: Hearing Before the Subcomm. on Oversight and Investigations of the House Comm. on Energy and Commerce*, 110th Cong., 1st Sess. 85, 88 (2007) (statement of Steven E. Nissen, Chairman of the Department of Cardiovascular Medicine at the Cleveland Clinic, and President of the American College of Cardiology ("Adverse event reporting is voluntary and studies show that only 1 to 10 percent of serious adverse events are ever reported to the Agency. Accordingly, the actual incidence of serious or life-threatened complications cannot be calculated accurately."); *see also* Barbara A. Noah, *Adverse Drug Reactions in Elderly Patients: Alternative Approaches to Postmarket Surveillance*, Vol. 33, No. 3, J. Health L. 383 (Summer 2000) ("Because the spontaneous reporting numerator represents only a tiny fraction of the actual number of ADRs, it remains difficult to accurately estimate the incidence of safety problems with many prescription drugs.").

[10] *See also In re Elan Corp. Sec. Litig.*, 543 F. Supp. 2d 187, 210 (S.D. N.Y. 2008) (plaintiffs did not allege that development of progressive multifocal leukoencephalopathy by one to two patients using Tysabri was statistically significant).

information within the "total mix." In the absence of statistical significance, the test would result in the exclusion of medical, biological and observational evidence of an association between a drug and an adverse health effect. The same evidence used by the FDA or manufacturers in resolving drug safety issues would, if not dependent upon a statistically significant number of reports, be treated as if immaterial as a matter of law. Materiality would be reduced to a rote and arbitrary calculation whereby reports of serious health effects, even death, only became material upon receipt of a single or small number of reports that tipped the balance and caused the data to cross the threshold of statistical significance.[11]

II. The Fact Intensive Approach Adopted by This Court in *Northway* Has Proved Sufficiently Robust to Resolve the Materiality of Quantitative Information, Including Adverse Event Reports

In rejecting the use of the bright-line test at issue in *Basic*, this Court left in place a fact intensive analysis for determining materiality. The approach has

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[11] *See* Stephen T. Ziliak and Deirdre N. McCloskey, THE CULT OF STATISTICAL SIGNIFICANCE, 28-29 (U. Mich. Press 2008) (five heart attacks by users of Vioxx not statistically significant and therefore treated as having "[no] significance, no risk to the heart" while eight heart attacks met standard of statistical significance).

proved sufficiently robust to resolve the materiality of quantitative data, including adverse event reports. Courts applying the fact intensive approach use the amount of the misstatement or the number of reports as a starting point. They then consider all other factors that have a bearing on the importance of the information to reasonable investors.

A. Quantitative Data Represents at Most a Starting Point for the Analysis of Materiality that Must Be Considered in Light of All Other Factors that Could Render the Information Important to Reasonable Investors

Courts have relied on the fact intensive analysis required by *Northway* and *Basic* to resolve the materiality of quantitative data such as earnings misstatements. Rejecting bright-line tests, they have characterized the amount of the misstatement as merely the starting point for the analysis. The quantitative data must be considered in light of all other factors that bear upon the importance of the information to reasonable investors. *See ECA & Local 134 IBEW Joint Pension Trust of Chi. v. JP Morgan Chase Co.*, 553 F.3d 187, 204 (2d Cir. 2009) (noting that the numerical threshold at issue was "a good starting place for assessing" materiality and that analysis required consideration of "qualitative factors that might contribute to a finding of materiality."); *Ganino v. Citizen Utils. Co.*, 228 F.3d 154, 164 (2d Cir. 2000) (rejecting application of a "bright-line test for

materiality" in context of alleged misstatement of earnings in favor of test requiring consideration of "all relevant circumstances."); *Gebhardt v. ConAgra Foods, Inc.*, 335 F.3d 824, 829 (8th Cir. 2003) (materiality of quantitative information must be considered in light of all "particular circumstances").

Thus, for example, the court in *In re Westinghouse Sec. Litig.*, 90 F.3d 696 (3d Cir. 1996) (Alito, J.), confronted allegations that misstatements concerning loan loss reserves and non-earning loans were immaterial as a matter of law. Although finding the alleged misstatement to be immaterial, the court expressly rebuffed the attempt to impose a bright-line test.

> [W]e also reject defendants' similarly categorical assertion that materiality must be quantified at a specified percentage of income or assets. Although "a 'rule of thumb' of 5-10 percent of net income is widely used as a general materiality criterion" in the accounting profession, . . . the question of materiality must be considered on a case-by-case basis under the standards set forth in *T.S.C. Industries* and our cases.

In re Westinghouse Sec. Litig., 90 F.3d at 714 n.14.

Likewise, the SEC relies on a fact intensive approach in determining materiality in the context of earnings misstatements. In Staff Accounting Bulletin 99 (1999) ("SAB 99"), the staff of the Commission

criticized the use by market professionals of quantitative thresholds for determining materiality.[12] SAB 99 acknowledged the appropriateness of "rules of thumb" as "an initial step in assessing materiality" but concluded that these thresholds cannot "appropriately be used as a substitute for a full analysis of all relevant considerations." *Id.* Instead, materiality requires consideration of other factors, whether, for example, the misstatement shifts a loss to a profit or masks a trend in earnings, that could render the information important to reasonable investors.

Using the fact intensive approach, courts have found small quantitative thresholds to be material when considered in conjunction with other relevant factors. *See United States v. Nacchio*, 519 F.3d 1140, 1162 (10th Cir. 2008), *rev'd on other grounds*, 555 F.3d 1234 (10th Cir. 2009), *cert. denied*, 130 S. Ct. 54 (2009) (jury could find that 4.2% shortfall in revenue was material based on arguments that "the shortfall had particular salience given the state of the economy and the industry"); *SEC v. Thielbar*, 2008 U.S. Dist.

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[12] While SAB 99 represents the views of the staff, the Commission has recognized the need to consider qualitative factors when determining the materiality of quantitative elements. *See In re AIG*, Exchange Act Release No. 48477 (admin. proc. Sept. 11, 2003) ("Materiality judgments involve both quantitative and qualitative considerations."); *see also* Speech by Arthur Levitt, Chairman, U.S. Securities and Exchange Commission, *The Numbers Game* (Sept. 28, 1998) ("Materiality is not a bright line cutoff of three or five percent. It requires consideration of all relevant factors that could impact an investor's decision.").

LEXIS 73906, *20-21 (D. S.D. 2008) (alleged misstatements as low as 1.97% and 1.10% of net income not immaterial as matter of law where company "was closely watched by analysts and investors alike" and net income preceding securities offering "would very likely influence the price at which these shares may sell"); *see also In re MBIA, Inc. Sec. Litig.*, 700 F. Supp. 2d 566, 584-85 (S.D. N.Y. 2010) (financial products were material to portfolio "even though [products] represented one percent of the $ 652 billion insured portfolio" where plaintiffs alleged that losses from these products "could significantly affect MBIA's triple-A ratings and creditworthiness").

Other courts have found similar thresholds to be immaterial in the absence of factors that would otherwise render the information important to reasonable investors. *See Parnes v. Gateway 2000, Inc.*, 122 F.3d 539, 547 (8th Cir. 1997) (2% overstatement of assets immaterial because a small increase in risk in a high-risk/high-yield company would not have a significant effect upon investor expectations); *Glassman v. Computervision Corp.*, 90 F.3d 617, 633 n.26 (1st Cir. 1996) (omission of information regarding 3% to 9% difference in backlog from quarter to quarter not material where variable had "minor predictive value" and "disclosure of a rough estimate of that variable's value can obviate the need for more specific disclosure").

The fact intensive framework set out in *Northway* and *Basic* has proved adequate to resolve the materiality of quantitative thresholds. Moreover,

despite the rejection of a bright-line approach, lower courts have acted as effective gatekeepers, eliminating on motions to dismiss those cases involving low quantitative thresholds that were otherwise unsupported by other factors demonstrating their importance to reasonable investors.

B. The Number of Adverse Event Reports Is at Most a Starting Point in Determining Materiality and Requires Consideration of All Other Factors that Could Render the Information Important to a Reasonable Investor

Courts addressing the materiality of drug safety data have applied the same fact intensive analysis set out in *Northway* and *Basic*. As with misstatements in earnings, the number of adverse event reports represents a starting place for analyzing materiality. The reports must be examined in light of all other factors that would render the information important to reasonable investors.

Carter-Wallace and *Oran v. Stafford,* 226 F.3d 275 (3d Cir. 2000), are not to the contrary. In *Carter-Wallace*, plaintiffs asserted that Felbatol, a drug used to treat epilepsy, caused aplastic anemia. The drug had "survived the extensive testing process" required by the FDA. *In re Carter-Wallace, Inc., Sec. Litig.*, 220 F.3d 36, 42 (2d Cir. 2000). From October 1993 to July 1994, Carter-Wallace received 57 adverse event reports, only six of which involved aplastic anemia. *See id.* at 38, 40.

The evidence of a connection between Felbatol and aplastic anemia was largely limited to six reports spread out over a nine month period for a thoroughly tested drug. In the absence of other factors suggesting a relationship between the drug and the adverse health condition, the court was left with little more than the quantity of the reports. In those circumstances, the quantitative data could only be material if, standing alone, it demonstrated a sufficient relationship between Felbatol and aplastic anemia. Such a relationship, according to the court, required evidence of statistical significance.

The opinion did not, however, treat statistical significance as the exclusive method of establishing materiality. Indeed, as the court subsequently noted, the issue was not statistical significance per se but whether the alleged facts showed a sufficient "connection" between the drug and the reported health effect. *See id.* at 42. Nothing in the opinion suggested that other factors bearing on the relationship between a drug and adverse effect report were entirely supplanted by a test of statistical significance.[13]

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[13] Had the court in *Carter-Wallace* intended to adopt a bright-line standard for materiality, it presumably would have sought to reconcile the approach with the reasoning in *Basic*. The case contains no such discussion or analysis. Moreover, at least one subsequent Second Circuit decision explicitly rejected application of bright-line test for materiality in the context of quantitative information. *See Ganino*, 228 F.3d at 154.

Similarly, in *Oran*, the court did not hold that the materiality of adverse event reports could only be determined through resort to statistical significance. In that case, the manufacturer of fen-phen disclosed reports from cardiologists with the Mayo Clinic and MeritCare Health Systems (Mayo data) that revealed incidents of heart valve abnormalities in users of fen-phen. The manufacturer described the evidence of any causal connection between fen-phen and heart valve abnormalities as "inconclusive." *Oran*, 226 F.3d at 283. The statement informed the market of the possibility of an association, the seriousness of the condition, the source of the reports, and the non-definitive nature of the evidence.

In considering whether the manufacturer also had an obligation to disclose other, earlier reports that contained much of the same information, the court characterized them as merely cumulative, something that had they been disclosed would have "led a reasonable investor to the same conclusion – that the relationship between the two drugs and heart valve disorders was still inconclusive." *Id.* at 284. The undisclosed reports, therefore, merely restated what the market already knew. With the plaintiffs unable to explain how the reports "would have added anything to the disclosures already made," materiality depended entirely on the number of reports. *Id.* at 284. In those circumstances, the court required a showing of statistical significance.

Oran did not restrict the definition of materiality but expanded it. The opinion clarified that adverse

event reports, standing alone, could be material, even absent other factors, upon a showing of statistical significance. What the court did not do was hold that statistical significance was the exclusive test for determining the materiality of adverse event reports. It applied a test of statistical significance only after observing that plaintiffs had presented no other basis for a finding of materiality. Indeed, the opinion did not rely on statistical significance in determining the materiality of other adverse event reports at issue in the case. *Id.* at 283 (Mayo data immaterial not because of lack of statistical significance but because of absence of a "negative effect on the company's stock price").

Both *Carter-Wallace* and *Oran* agree that adverse reports, standing alone, can be material if statistically significant. They do not, and lower courts have not read them to, impose a bright-line test that otherwise dispenses with the fact intensive analysis set out in *Northway* and *Basic*. *See In re Medtronic Inc., Sec. Litig.*, 618 F. Supp. 2d 1016, 1024 (D. Minn. 2009) ("[s]tatistical significance, however, is not a bright-line rule because materiality 'is a flexible, fact-based determination.'") (*quoting In re Bayer AG Sec. Litig.*, 2004 U.S. Dist. LEXIS 19593, *27 (S.D. N.Y. Sept. 30, 2004)); *Twinde v. Threshold Pharms., Inc.*, 2008 U.S. Dist. LEXIS 58619, *35 (N.D. Cal. 2008) (noting that "statistically significant test results are conclusive" but that "non-statistically significant [serious adverse events] together with other evidence" can be material); *accord, In re Elan Corp. Sec. Litig.*,

543 F. Supp. 2d 187, 210 (S.D. N.Y. 2008); *In re Bausch & Lomb, Inc. Sec. Litig.*, 592 F. Supp. 2d 323, 350 (W.D. N.Y. 2008); *In re Pfizer, Inc. Sec. Litig.*, 584 F. Supp. 2d 621, 636 (S.D. N.Y. 2008).

Courts, then, have applied the fact intensive approach to resolve the materiality of adverse event reports. The number of reports may represent a starting place for the analysis but must be considered in the context of all other factors that render the information important to reasonable investors.

III. Application of the Fact Intensive Analysis Will Not Impose an Excessive Disclosure Burden on Manufacturers or Result in the Inundation of Investors with Excessive and Unfiltered Information

A fact intensive analysis does not impose an unfair burden on manufacturers and will not result in excessive, unfiltered disclosure to investors.

To be sure, *Northway* expressed concern with a standard that could generate an "avalanche of trivial information. . . ." 426 U.S. at 448. The concern, however, arose in the context of a test that sought to extend the definition of materiality to information that "might" be important to a reasonable investor. This Court addressed that matter by rejecting the formulation in favor of a "would" and "actual significance" test. As *Basic* noted, this standard effectively filtered out the "essentially useless information that a reasonable investor would not consider significant,

even as part of a larger 'mix' of factors to consider in making his investment decision." *Basic*, 485 U.S. at 234.

The standard does not, therefore, impose on manufacturers an obligation to disclose all adverse effect reports. Such an assertion conflates the need to inform the market of health risks with the obligation to reveal every report. In many instances, the reports will be immaterial, either because the effects are not serious, earnings from the drug are not material, or the reports have no other significance and are merely cumulative. *See Oran*, 226 F.3d at 284.

Rejection of the test of statistical significance will also not provide manufacturers with "a strong incentive simply to disclose all" reports. Pet. Br. 29. Lower courts already routinely apply the *Northway* standard in determining the materiality of adverse event reports. This has not resulted in manufacturers making all such reports available to the public. Reaffirming the longstanding standard set out in *Northway* will leave the law unaltered and not necessitate any change in existing disclosure practices by manufacturers.

Likewise, even if voluntary disclosure of adverse event reports does occur, the case has not been made that this will harm investors. *Northway* did recognize that excessive disclosure could, in some instances, interfere with informed decision making. *See* 426 U.S. at 448-49. But the concern arose in context of a proxy solicitation. In those circumstances, shareholders are

asked to make an informed decision based upon the information included within the materials distributed to them by the company. *See* J. Robert Brown, Jr., Chapter 5: Materiality, THE REGULATION OF CORPORATE DISCLOSURE, at pp. 5-22.1 – 5-26 (Aspen Business, 3d ed. 2009). Including excessive amounts of unrelated information within the proxy materials could potentially interfere with the decision making process.

This case, however, involves disclosure to the market, not to shareholders. Market disclosure typically occurs through press releases, SEC filings, or postings on the Internet. *See Commission Guidance on the Use of Company Web Sites*, Exchange Act Release No. 58288 (Aug. 7, 2008) (providing guidance on the use of web sites to meet requirements under, among other things, the antifraud provisions of the federal securities laws). The information is not sent directly to shareholders but is available to, and filtered by, analysts and other market professionals who have an economic incentive to accurately reflect the information in share prices. *See* THE REGULATION OF CORPORATE DISCLOSURE, pp. 8-5 – 8-6. The safety data disclosed by manufacturers will undergo the same filtering process, presumably improving the efficiency of share prices. Consistent with this approach, Congress has encouraged the Securities and

Exchange Commission to develop a system of real-time disclosure for public companies.[14]

In any event, the possibility of harm resulting from disclosure is not, as *Basic* reminds, appropriately resolved under the rubric of materiality. This concern is better addressed in the context of the duty to disclose. 485 U.S. at 235. As this Court has noted often, silence absent a duty to disclose does not violate the antifraud provisions. *See Chiarella v. United States*, 445 U.S. 222, 230 (1980); *Basic*, 485 U.S. at 239 n.17; *see also Oran*, 226 F.3d at 285 ("Even non-disclosure of material information, e.g., deaths connected to a drug, will not give rise to liability under Rule 10b-5 unless the defendant had an affirmative duty to disclose that information.").[15]

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[14] *See* Section 409, Corporate and Criminal Fraud Accountability Act of 2002 (Sarbanes-Oxley), Pub. L. No. 107-204, 116 Stat. 745 (July 30, 2002) (amending Section 13 of the Securities Exchange Act to allow SEC to require real time disclosure of "material changes in the financial condition or operations of the issuer"). Indeed, some have called for increased disclosure of adverse health information. *See* James M. Wood & Roxanne M. Gariby, *Hoarding Away Science: Towards a More Transparent View of Health and Online Registries for Independent Postmarket Drug Research*, 60 FOOD & DRUG L.J. 547, 555-556 (2005) ("Online transparency of all results, clinical and post-market, regardless of the source, achieves the goal of not only identifying all information about the safety and efficacy of a prescription medicine, but also would have the additional benefit of preventing unnecessary and costly duplication of research.").

[15] The argument that over-disclosure will occur because of concern about liability under the antifraud provisions of the

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Finally, the test of statistical significance also will not provide the benefits ordinarily associated with a bright-line test. Some courts characterize the test as a factual question. *See Pfizer,* 584 F. Supp. 2d at 635-36 ("[T]he Court cannot determine as a matter of law whether such links were statistically insignificant because statistical significance is a question of fact."); *accord, City of Livonia Employees' Ret. Sys. v. Wyeth*, 2010 U.S. Dist. LEXIS 107729, *19 (S.D. N.Y. 2010); *see also Union Carbide Chems. & Plastics Tech. Corp. v. Shell Oil Co.*, 2004 U.S. Dist. LEXIS 10730, *21 (D. Del. 2004) ("Statistical significance . . . is a question of fact for the jury as it is an issue of evidentiary weight"), *vacated in part on other grounds*, 425 F.3d 1366 (Fed. Cir. 2005); *Cook v. Rockwell*, 580 F. Supp. 2d 1071, 1102-03 (D. Colo. 2006) ("statistical significance or insignificance of [epidemiologist's] results may affect the weight given to his testimony, but does not determine its admissibility under Rule

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federal securities laws is not supported by the trend in the number of securities class action lawsuits. The number is falling. In 2009, filings dropped to the second lowest number since 1997 when comprehensive statistics were first maintained. *See Securities Class Action Clearinghouse* (168 securities class action lawsuits filed in 2009). This was true despite arguably auspicious circumstances for such suits, including the financial crisis and significant drop in share prices. *See Report of the New York Stock Exchange Commission on Corporate Governance*, September 23, 2010, at 11 ("At its nadir, the Dow Jones Industrial Average hit a 12-year low of approximately 6,600 in March 2009"). Moreover, the decline has continued in 2010. *See Securities Class Action Clearinghouse* (148 securities class action law suits) (last update: Nov. 8, 2010).

702."). Thus, while effectively eliminating information important to reasonable investors, the uncertainty of the test will itself generate legal challenges. *See In re Nuvelo, Inc.*, 668 F. Supp. 2d 1217, 1230 (N.D. Cal. 2009).

Application of a fact intensive analysis in determining the materiality of adverse event reports will not result in untoward harm to investors or manufacturers. Moreover, to the extent manufacturers opt to disclose all such reports to the market, the information will be filtered through analysts and market professionals and presumably result in more efficient share prices.

IV. Application of a Fact Intensive Analysis in this Case Creates a Factual Question as to the Materiality of the Association Between Zicam and Anosmia

In applying a fact intensive analysis to adverse event reports, courts and the FDA have relied on a variety of factors when assessing the importance of the information. A non-exclusive list of factors might include:

1. The nature and rarity of the condition reported;[16]

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[16] *Drug Safety, supra* note 8, at 25 n.44.

2. The person or source originating the adverse event reports, with particular weight given to those submitted by health care professionals;[17]

3. The existence of scientific literature supporting the possibility of an association;[18]

4. A temporal association between the administration of the drug and the onset of the adverse event;[19]

5. A significant change in the rate of adverse event reports;[20]

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[17] *Reporting Adverse Drug and Medical Device Events*, Council of Ethical & Judicial Affairs Report B – A-93 (1993) (CEJA Report B – A-93), *reprinted in* American Med. Ass'n, *Reporting Adverse Drug and Medical Device Events: Report of the AMA's Council on Ethical and Judicial Affairs*, 49 FOOD & DRUG L.J. 359, 362 (1994) (discussing the importance of reports from physicians and noting that the "impact of physicians' reports is reflected in the observation that although they constitute only a fraction of reports received, physicians' reports account for a much greater proportion of labeling changes.").

[18] *See* Lance L. Shea, Andre Hanson, Tiffany M. Guglielmetti, and Kimberly Levy, *Cause and Effect? Assessing Postmarketing Safety Studies as Evidence of Causation in Products Liability Cases*, 62 FOOD & DRUG L.J. 445, 447 (2007) ("FDA scientists have access to the world's peer-reviewed, published literature, which they review to assess for postmarketing safety issues.") (*Cause and Effect*).

[19] *See Bonner v. ISP Techs., Inc.*, 259 F.3d 924, 932 (8th Cir. 2001) ("Under some circumstances, a strong temporal connection is powerful evidence of causation.").

[20] *See Cause and Effect*, *supra* note 18, at 446 ("FDA evaluates spontaneous reporting data from the AERS to identify

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6. The internal reaction of the manufacturer to the adverse event reports;[21]

7. The number of adverse event reports for other drugs used for the same or similar treatment;[22]

8. The existence of other studies, including observational, epistemological, or controlled studies, that have a bearing on the safety of the drug at issue;[23]

9. The existing safety profile of the drug;[24]

10. Concerns raised by the FDA;[25]

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any serious, rare or unexpected adverse events, or an increased incidence of events.").

[21] *See In re Bayer AG Sec. Litig.*, 2004 U.S. Dist. LEXIS 19593, *28-29 (S.D. N.Y. 2004) (adverse reports caused company executives to question viability of drug).

[22] *See* Warning Letter, from Deborah M. Autor, Esq., Director, Office of Compliance, Center for Drug Evaluation and Research, U.S. Food and Drug Administration, to William J. Hemelt, Acting President, CFO and COO, Matrixx Initiatives, Inc., June 16, 2009 ("By comparison, FDA has received few reports of anosmia associated with other widely-used intranasal products for treatment of the common cold that are marketed subject to approved NDAs or according to an OTC drug monograph.") ("Matrixx Warning Letter").

[23] *See Drug Safety, supra* note 8, at 4, 6-7.

[24] *See In re Carter-Wallace Sec. Litig.*, 220 F.3d at 37 (noting "unprecedented safety profile" of FDA approved drug).

[25] *See In re Connetics Corp. Sec. Litig.*, 542 F. Supp. 2d 996, 1010 (N.D. Cal. 2008) (FDA's statement that drug had "possible carcinogenic effect" characterized as "significant and material").

11. Experiences in foreign markets;[26] and

12. A decline in share prices when the adverse event reports are made public.[27]

Multiple factors may appear in any given case and must be collectively weighed to determine whether the reports would be important to a reasonable investor.

In analyzing the factors in this case, the Complaint contains allegations of somewhere around 20 specific reports involving a loss of smell by users of Zicam. In addition, the Complaint alleges that Timothy L. Clarot, the Company's Vice President, Research and Development, stated that Matrixx had received "complaints from other customers who experienced a loss of smell following use of Zicam nasal gel" and that the complaints had occurred as early as 1999. *See* Compl. ¶26. Aware of these "complaints," Matrixx "hired a consultant to review the product" *id.* and considered undertaking "animal studies." Compl. ¶27.

The number of reports, however, represents only a starting point. The Complaint sets out other factors that must be considered in determining whether the

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[26] Jill D. Jacobson and David Feigal, *Red Sky in the Morning: Modifying Prescription Drug Labels as a Result of Postmarket Surveillance*, 62 FOOD & DRUG L.J. 529 (2007) ("Experiences in foreign countries also provide useful information.").

[27] *See Oran*, 226 F.3d at 283.

information would be important to a reasonable investor.

First, the reported condition, anosmia, is described as "rare." *See* Compl. ¶¶24, 64.

Second, the Complaint contains allegations of a temporal connection between the administration of Zicam and the loss of smell. An abstract for a presentation to the American Rhinologic Society described a patient who, upon the use of the drug, experienced an "immediate, severe burning" followed by a loss of smell. Compl. ¶28. Researchers further reported that there were a number of "other Zicam users with similar symptoms as of September of 2003." *Id.*

Third, Zicam is a homeopathic drug sold over the counter and, as such, was not, during the class period, required to submit to the rigorous safety testing mandated by the FDA for new drug applications. In describing statements that Zicam caused anosmia as "completely unfounded and misleading," Compl. ¶7, therefore, Matrixx was not relying on a determination by the FDA that the drug had an "'acceptable safety profile.'" *Oran*, 226 F.3d at 285. Matrixx did reveal that "the safety and efficacy of zinc gluconate for the treatment of symptoms related to the common cold have been well established in two double-blind, placebo-controlled, randomized clinical trials . . . " Compl. ¶38. Because clinical trials often have a relatively small number of subjects, they may

not be able to detect "rare" conditions.[28] As the lower court observed, Matrixx did not "state that any tests established that the application of zinc gluconate to the nose is safe." *Siracusano v. Matrixx Initiatives, Inc.*, 585 F.3d 1167, 1178 n.6 (9th Cir. 2009).[29]

Fourth, the reports were supported by scientific studies linking zinc to a loss of smell. Although the studies involved zinc sulfate (*see* Compl. ¶26) and Zicam contained zinc gluconate (*see* Compl. ¶3), they apparently provided evidence of a possible biological basis for the requisite association.[30]

Fifth, the reports set out in the Complaint came from health care professionals and lawyers (in the form of litigation). One of the professionals, Dr. Alan Hirsch M.D., F.A.C.P., was the Neurological Director of the Smell & Taste Treatment and Research Foundation, Ltd. Compl. ¶25.

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[28] CEJA Report B – A-93, *supra* note 17 ("in order to detect the difference between an adverse reaction incidence rate of $^1/_{8000}$ and $^1/_{10,000}$, some 306,000 patients would have to be observed, far more than any study could achieve.").

[29] Similarly, the Matrixx Warning Letter revealed that the FDA was "not aware of any data establishing that the Zicam Cold Remedy intranasal products are generally recognized as safe and effective for the uses identified in their labeling." Matrixx Warning Letter, *supra* note 22.

[30] The Matrixx Warning Letter subsequently issued by the FDA acknowledged that "there is evidence in the published scientific literature that various salts of zinc can damage olfactory function in animals and humans." Matrixx Warning Letter, *supra* note 22.

Sixth, Matrixx learned about some of the reports of anosmia through research conducted by Dr. Bruce Jafek, Miriam R. Linschoten and Bruce W. Morrow of the University of Colorado School of Medicine, Department of Otolaryngology. The results were presented at a meeting of the American Rhinologic Society. Compl. ¶29.

Seventh, the internal response by Matrixx suggested an awareness of a possible link between Zicam and anosmia. As early as September 2002, a Matrixx official acknowledged that the Company had hired a consultant "to review the product" and invited Miriam R. Linschoten from the University of Colorado Health Sciences Center to "participate in animal studies that Matrixx was planning to conduct." Compl. ¶¶26, 27. The Company also convened a meeting of scientists and physicians in 2004 "to review current information on smell disorders." Compl. ¶45.

Eighth, share prices declined when an article appeared in the Dow Jones Newswire on Jan. 30, 2004, reporting that the FDA was looking into complaints that "an over-the-counter common-cold medicine manufactured by" Matrixx may cause "some users to lose their sense of smell," Compl. ¶¶40, 41, and again following a report on Feb. 6, 2004, on *Good Morning America*, about "the connection between Matrixx's zinc gluconate and anosmia." Compl. ¶¶42, 43.

* * *

To impose a requirement that reports must be statistically significant overlooks the central question in determining materiality: whether it is substantially likely that a reasonable investor would consider the omitted or misstated facts to have significantly altered the total mix of available information. The information need not have produced a different outcome but only have assumed "actual significance" in the deliberative process. The analysis is, as *Northway* rightfully recognized, a subtle one that requires a "delicate assessment of the inferences" in the context of all factors that could render the information important to a reasonable investor. This cannot be done through resort to a single test or factor.

Section 10(b) is part of a statutory scheme that has as a "fundamental purpose" the reliance on full disclosure. *See Central Bank of Denver, N.A. v. First Interstate Bank of Denver, N.A.*, 511 U.S. 164, 171 (1994). Disclosure in turn helps "stimulate and stabilize the markets" and "inspire investor confidence in the integrity of the markets." Elizabeth Nowicki, *10(b) or Not 10(b)? Yanking the Security Blanket for Attorneys in Securities Litigation*, 3 COLUM. BUS. L. REV. 637, 690 (2004). *Basic* rejected a rigid and underinclusive test for materiality aware that, without accurate and complete disclosure, investors would "'be less likely to invest, thereby reducing the liquidity of the securities markets to the detriment of investors and issuers alike.'" 485 U.S. at 235 n.12 (*quoting In re Carnation Co.*, Exchange Act Release No. 22214

(1985)). A test of statistical significance raises the same concerns.

The standard in *Northway* has functioned effectively for more than three decades.[31] To the extent that there is a need for intervention in this area, the matter is better left to the SEC, where the complexities attendant with the adoption of a materiality standard incorporating statistical significance can better be addressed.[32] At least in the first instance, administrative agencies have the expertise to frame the salient issues and clarify the standards for interpreting the statutes that Congress has charged them to enforce. *See Chevron U.S.A. Inc. v. NRDC*, 467 U.S. 837, 843 (1984). Indeed, here, the administrative agency promulgated the regulation that is the subject of the parties' dispute, Rule 10b-5.

CONCLUSION

The court below applied the correct analysis, examining not only the number of reports but also the other factors that could render the information important to a reasonable investor. *Amici* therefore

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[31] *See Jones v. Harris Assocs. L.P.*, 130 S. Ct. 1418, 1430-31 (2010) ("The *Gartenberg* standard . . . may lack sharp analytical clarity, but . . . has provided a workable standard for nearly three decades.").

[32] The SEC has, for example, adopted a rule providing a safe harbor for the disclosure of forward-looking statements. *See* Rule 175, 17 C.F.R. § 230.175.

respectfully urge this Honorable Court to affirm the ruling of the United States Court of Appeals for the Ninth Circuit.

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AMICUS CURIAE BRIEF

No. 09-1156

IN THE

Supreme Court of the United States

MATRIXX INITIATIVES INC., ET AL.,

Petitioners,

v.

JAMES SIRACUSANO and NECA-IBEW PENSION FUND,

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

BRIEF OF PRODUCT LIABILITY ADVISORY COUNCIL, INC. AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

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This brief is filed on behalf of the Product Liability Advisory Council, Inc. as *amicus curiae* in support of Petitioners.[1]

INTEREST OF *AMICUS CURIAE*

Amicus Curiae Product Liability Advisory Council, Inc. ("PLAC") is a non-profit association of over 100 corporate members representing a broad cross-section of American and international product manufacturers,[2] who seek to contribute to the improvement and reform of law in the United States and elsewhere, especially that governing the liability of manufacturers of products. Several hundred leading product liability defense attorneys in the country are also sustaining (non-voting) members of PLAC. Since 1983, PLAC has filed more than 850 briefs as *amicus curiae* in both state and federal courts, including more than eighty in this Court, presenting the perspective of product manufacturers seeking fairness and balance in the application and development of the law as it affects product liability.

PLAC is well situated to address the issues in this case. Many PLAC members or their related

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1 *Amicus* has notified the parties of its intention to file a brief as *amicus curiae*, blanket consent has been granted and filed. No counsel for a party in this case authored this brief in whole or in part, and no person or entity other than *Amicus*, its members, or its counsel made a monetary contribution to the preparation or submission of this brief.

2 A list of PLAC's current corporate membership is included as Appendix A to this brief.

entities are subject to the federal securities laws, including the disclosure requirements outlined in Section 10(b) of the Securities Exchange Act of 1934 and the Securities and Exchange Commission's Rule 10b-5. Many PLAC members are also subject to reporting obligations similar to those at issue here, and so this topic is of substantial interest not only to PLAC's members in the pharmaceutical industry but also those in a wide range of other manufacturing industries. PLAC respectfully submits this brief as *amicus curiae* to describe for the Court some of the other regulatory reporting schemes which could give rise to securities disclosure issues like those presented in this case.

SUMMARY OF ARGUMENT AND INTRODUCTION

In this case, the parties dispute whether Petitioners, Matrixx Industries, Inc., et al., are liable under § 10(b) of the Securities Exchange Act of 1934, 15 U.S.C. § 78j(b), and Securities Exchange Commission Rule 10b-5, 17 C.F.R. § 240.10b-5, for failing to inform investors of certain "adverse event" reports even though there was no statistically significant link between the use of Matrixx's drug, Zicam Cold Remedy, and the undisclosed events.

There is a world of difference between the intended users of information disclosed under the federal securities laws and information reported to regulators, such as the Food and Drug Administration ("FDA"), charged.

For purposes of liability under § 10(b) and Rule 10b-5, "materiality depends on the significance the reasonable investor would place on the withheld

or misrepresented information." *Basic Inc. v. Levinson*, 485 U.S. 224, 240 (1988). This Court's decisions on materiality recognize that "[s]ome information is of such dubious significance that insistence on its disclosure may accomplish more harm than good." *TSC Indus., Inc. v. Northway, Inc.*, 426 U.S. 438, 448 (1975). The role of the materiality requirement is to "filter out essentially useless information that a reasonable investor would not consider significant." *Basic*, 485 U.S. at 234. A low standard of materiality poses risks for issuers and investors alike; in order to avoid liability for "insignificant" omissions or misstatements, corporations and their management may overwhelm investors in "an avalanche of trivial information—a result that is hardly conducive to informed decisionmaking." *TSC Indus.*, 426 U.S. at 448-49.

By contrast, regulatory agencies, such as the FDA, the National Highway Traffic Safety Administration ("NHTSA"), or the Consumer Product Safety Commission ("CPSC"), have statutory mandates to protect the public. Their responsibilities are fulfilled in part by identifying potential patterns and problems from an aggregate of information and are specifically staffed and funded to allow them to analyze and process the information. Adverse event and other forms of regulatory reporting by manufacturers and others is designed to assist this work. By and large, the reporting standards are explicitly broad and over-inclusive. A manufacturer typically will need to make such a report before any causal connection has been hinted at, let alone established, between the event and the use of the manufacturer's product and even before the

manufacturer has had a chance to investigate whether the event actually occurred. *See, e.g.*, 16 C.F.R. § 1115.4(e) ("[S]ubject firms should report [to the CPSC even] if in doubt as to whether a defect exists."). In many cases, agencies also encourage direct reporting by consumers, with little to no oversight of the accuracy of what are essentially anecdotes.

Thus, almost as a rule, isolated adverse event and other regulatory reports are of questionable value to investors, for whom such information will have no intelligible context. "Materiality" acts as a "filter" of such "essentially useless information." *Basic*, 485 U.S. at 234. Regulators, on the other hand, seek out bits and pieces of information which may be premature, marginal, incomplete, or unreliable.

The Courts of Appeals for the First, Second and Third Circuits have recognized the counter-productive impact of requiring disclosure of "adverse events" reported to (or maintained for) regulators where there is no allegation that the undisclosed adverse event reports demonstrated a statistically significant relationship between the product and the alleged event. *See, e.g., New Jersey Carpenters Pension & Annuity Funds v. Biogen Idec Inc.*, 537 F.3d 35 (1st Cir. 2008); *In re Carter-Wallace, Inc. Sec. Litig.*, 220 F.3d 36 (2d Cir. 2000); *Oran v. Stafford*, 226 F.3d 275 (3d Cir. 2000). As discussed at length in Petitioners' Brief, that rule provides a scientifically intelligible basis for determining when reports become material and can assist investors in understanding which regulatory reports matter and when.

By contrast, the Ninth Circuit's view of materiality in this case would call for disclosure of regulatory reports, even where there is (or can be) no allegation that the events at issue had any meaningful scientific relationship with use of a drug. *Siracusano v. Matrixx Initiatives, Inc.*, 585 F.3d 1167 (9th Cir. 2009). The court held that it could not "as a matter of law" determine whether studies or reports were statistically insignificant because "'statistical significance is a question of fact.'" *Id.* at 1179 (quoting *In re Pfizer Inc. Sec. Litig.*, 584 F. Supp. 2d 621, 635-36 (S.D.N.Y. 2008)). Thus, Ninth Circuit's decision "left to the trier of fact" the question of whether a handful of reports of adverse events could show a "statistically significant link" with a drug used millions of times. *Id.* Not surprisingly, the imposition of such a rule could force manufacturers to disclose regulatory reports without regard to their ultimate scientific value or their intelligibility to investors.

The implications of the Ninth Circuit's decision reach beyond Zicam and over-the-counter medications to a host of industries who are required to report adverse events which may have only a tenuous link to a company's products. Over-disclosure and disclosure of information that cannot be useful to the reasonable investor would be the likely results. As urged by Petitioners, the "statistical significance" standard used in the First, Second, and Third Circuits provides a meaningful guidepost for gauging materiality in this context and should be adopted by the Court.

ARGUMENT

The Ninth Circuit's decision, if allowed to stand, would have implications extending far beyond over-the-counter cold medicines. Manufacturers of products as diverse as hearing aids, infant formula, car batteries, veterinary medicines and motorcycles could conclude that their investors must be informed of "reportable" events, which, by definition, may never have happened.

I. Implications of Ninth Circuit's Decision for Pharmaceuticals and Over-the-Counter Drugs

The reporting requirements at issue in this case apply to pharmaceuticals generally, not just over-the-counter cold medicines, as manufacturers of both prescription and non-prescription drugs have ongoing and periodic obligations to report adverse events to the FDA.

Drug manufacturers, packagers and distributors are required to inform the FDA of "adverse drug experiences" even if they are "not considered drug related." 21 C.F.R. § 314.80(a); *see also* 21 U.S.C. § 379aa(a)-(b); 21 U.S.C. § 355(k). Reportable adverse events expressly include events that may be attributable to "overdose" and "abuse of the drug." 21 U.S.C. § 379aa(1); *see also* 21 C.F.R. § 314.80(a). Experiences which are both "serious"[3]

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[3] A "serious adverse" drug experience is one that results in death, a life-threatening experience, hospitalization, disability, a congenital anomaly or birth defect or which requires medical intervention to prevent one of these outcome. 21 U.S.C. § 379aa(a)(3); 21 C.F.R. § 314.80(a).

and "unexpected"[4] must be reported within fifteen calendar days. 21 C.F.R. § 314.80(c).[5] All other adverse drug experiences for drugs approved through the new drug application process are to be compiled into periodic reports for the FDA quarterly or annually, based on how long the drug has been approved. 21 C.F.R. § 314.80(c)(2)(i). Records of adverse drug events involving grandfathered products must be maintained for ten years. 21 C.F.R. § 310.305(f). As part of their regulatory obligations, manufacturers are expected to seek out information about their products from various sources, both "foreign and domestic," including from scientific, literature, and unpublished scientific papers. *See* 21 C.F.R. § 314.80(b). This information helps the FDA monitor the safety of all marketed drug products. *See, e.g.*, Final Rule, Adverse Drug Experience Reporting Requirements for Marketed Prescription Drugs Without Approved New Drug or Abbreviated New Drug Applications, 51 Fed. Reg. 24476-01 (July 3, 1986). If manufacturers fall short in their reporting or record-keeping obligations, the FDA may withdraw the approval or prohibit continued marketing of their drug. 21 C.F.R. § 314.80(j).

In addition to reports received from manufacturers in compliance with their regulatory obligations, the FDA receives reports directly from

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[4] An "unexpected" adverse drug experience is one not currently listed in the drug's labeling. 21 C.F.R. § 314.80(a).

[5] After filing this initial report, manufacturers are expected to continue investigating the event and to file subsequent followup reports. 21 C.F.R. § 314.80(c)(1)(ii).

health care providers and consumers[6] about prescription and over-the-counter drugs and therapeutic biological products.[7] The total volume of adverse event reports each year can be staggering. In 2009 alone, the FDA received over 580,000 reports.[8]

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[6] These "direct" reports are received "via letters, faxes, telephone calls, emails, or directly over computer modems" and "can include anything from a report of a serious, unexpected [adverse drug reaction] to a report of a well-known, trivial [reaction]." *Drug-Related Adverse Events: Hearing Before the S. Comm. on Health Education Labor & Pensions* (statement of Janet Woodcock, Director, Center for Drug Evaluation and Research, Food and Drug Administration (Feb. 1, 2000), http://www.fda.gov/NewsEvents/Testimony/ucm115007.htm [hereinafter *Woodcock Testimony*].

[7] *See Reports Received and Reports Entered into AERS by Year*, FOOD AND DRUG ADMINISTRATION, http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm070434.htm (last visited Aug. 27, 2010) [hereinafter "*Reports Received and Reports Entered into AERS*"]. Biological products are a subset of drugs and include vaccines and most protein products. *Frequently Asked Questions About Therapeutic Biological Products*, FOOD AND DRUG ADMINISTRATION, http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/ucm113522.htm (last visited Aug. 27, 2010). Like other drugs, they are used "for the treatment, prevention or cure of disease in humans. . . [but] are generally derived from living material—human, animal, or microorganism." *Id.*

[8] *See Reports Received and Reports Entered into AERS*. Of these, 6% were direct reports from consumers and health care providers, 57% were fifteen-day reports of serious adverse events, and 37% were periodic reports. *Id.* There is

The National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, § 2125, 100 Stat. 3743, 3774-78 (1986), requires health professionals and vaccine manufacturers to file adverse event reports ("AERs") with the U.S. Department of Health and Human Services ("HHS") using the Vaccine Adverse Event Reporting System ("VAERS"), which was created in 1990. *See* 42 U.S.C. § 300aa-27(a)(2). As with other reporting systems, VAERS is intended simply to "provid[e] health scientists with signals about possible adverse events" to be followed by controlled epidemiological studies before action is taken.[9] The agencies encourage the reporting of "*any* clinically significant medical event that occurs after vaccination, even if the reporter cannot be certain that the event was caused by the vaccine."[10]

About 30,000 reports regarding vaccines are received each year. While some involve serious side effects, about eighty-five to ninety percent describe "mild adverse events such as fever, local reactions,

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some duplication in these numbers "due to factors such as follow-up reports received on a case or different persons reporting on the same patient case." *Adverse Event Reporting System (AERS) Statistics*, FOOD AND DRUG ADMINISTRATION (Mar. 31, 2010) http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm070093.htm [hereinafter *Adverse Event Reporting System*].

[9] *About the VAERS Program*, VACCINE ADVERSE EVENT REPORTING SYSTEM, http://vaers.hhs.gov/index/about/index (last visited Aug. 27, 2010).

[10] *Id.*

and episodes of crying or mild irritability."[11] The agencies that established and use the system—the FDA, the HHS, and the Centers for Disease Control and Prevention—recognize that while VAERS "enables the early detection of signals that can then be more rigorously investigated," the reports in themselves "can rarely provide definitive evidence of causal associations."[12]

The FDA plainly seeks over-inclusive data to satisfy its broad regulatory role and to stay informed of potential and even remote product hazards. *See* Federal Food, Drug, and Cosmetic Act, 52 Stat. 1040 (1938); 21 U.S.C. § 393(b)(2) (defining the FDA's "[m]ission" to include "protect[ing] the public health by ensuring that . . . drugs are safe and effective" and that "there is reasonable assurance of the safety and effectiveness of devices intended for human use").[13] Towards this end, for example, an adverse event involving grandfathered products is reportable as long as it was somehow "associated with the use of the drug in humans." 21 C.F.R. § 310.305(a)-(b);

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[11] *Id.*

[12] *Id.*

[13] Over-inclusiveness is sensible in light of the fact that these reports are assessed by trained professionals who, unlike the lay investor, can sift the wheat from the chaff. *See Adverse Event Reporting System*, *supra* note 8 (explaining that AERs are "evaluated by clinical reviewers" who are able to identify "potential safety concern[s]" that require "further evaluation"); *see also Woodcock Testimony*, *supra* note 6.

see also 21 C.F.R. § 314.80(a).[14] The FDA's analysis of the AERs forms an integral part of its "routine safety monitoring" and provides it with a baseline of data from which it can identify "potential safety issues" that require further monitoring.[15] An "adverse event" has no "cause-and-effect implication" but "simply describes some sort of harm that occurs during healthcare."[16]

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[14] *See also* 21 U.S.C. § 379aa(g) ("The submission of any adverse event report in compliance with this section shall not be construed as an admission that the nonprescription drug involved caused or contributed to the adverse event."); 21 C.F.R. § 314.80(k) ("A report or information submitted by an applicant . . . does not necessarily reflect a conclusion by the applicant or FDA that the report or information constitutes an admission that the drug caused or contributed to an adverse effect."); *Adverse Event Reporting System*, *supra* note 8 (noting that "there is no certainty that the reported event was actually due to the product" because the agency "does not require that a causal relationship between a product and event be proven and reports do not always contain enough detail to properly evaluate an event").

[15] *See Potential Signals of Serious Risks*, FOOD AND DRUG ADMINISTRATION, http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm082196.htm (last visited Aug. 27, 2010).

[16] *Woodcock Testimony*, *supra* note 6; *see also Adverse Event Reporting System*, *supra* note 8 (noting that the adverse event reporting system is a useful tool because it helps the FDA "look[] for new safety concerns that might be related to a marketed product, evaluat[e] a manufacturer's compliance [with] reporting regulations and respond[] to outside requests for information").

Courts have, as Petitioners have demonstrated, accorded limited probative value to AERs in establishing legal causation,[17] while recognizing their importance to the FDA's regulatory mandate.[18] This reporting standard does not and is not intended to serve as a proxy for the materiality standard.

II. Implications of Ninth Circuit's Decision for Other FDA-Regulated Products

Such reporting requirements are not limited to prescription and over-the-counter drugs. The FDA

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[17] *See, e.g., Pauley v. Bayer Corp.*, No. 2729, 2006 WL 463866, at *2 (Pa. Com. Pl. Jan. 26, 2006) ("AERS data has not been scientifically or otherwise verified; it is not the product of laboratory research or any type of controlled study. It is merely the compilation of experiential reports submitted by those in the field."); *Swallow v. Emergency Medicine*, 67 P.3d 68, 73 (Idaho 2003) (affirming decision to exclude expert testimony based on AERs because "there was no showing . . . [that they] were statistically significant"); *Ryman v. Sec'y of Dep't. of Health & Human Servs.*, 65 Fed. Cl. 35, 39-40 (2005) (VAERS evidence "is not reliable" because "reports can be filed by anyone," and "[t]he information provided is often insufficient to make an assessment.").

[18] *See, e.g., Hagaman v. Merrell Dow Pharm., Inc.*, No. 84-2202-S, 1987 WL 342949, at *8 (D. Kan. June 26, 1987) (noting that while "the technical completeness of [AERs] leaves much to be desired" and the FDA "does not place much faith in [their] usefulness . . . as an aid in determining causation," they are nonetheless useful "as a red flag mechanism that could, in certain instances, tip off the drug manufacturers and the medical community that a certain drug may have some contraindications").

regulates a wide range of products such as food, radiation-emitting products, infant formula veterinary medicines, medical devices, and animal feed[19] which are, to a lesser or greater extent, subject to adverse event reporting requirements.

For example, the FDA receives AERs from manufacturers concerning "medical devices," a category which runs from "simple tongue depressors and bedpans to complex programmable pacemakers with micro-chip technology and laser surgical devices," and includes products for professional and home care use, such as syringes, stents, catheters, defibrillators, hearing aids, glucose meters, wheel chairs, and heating pads.[20] Medical devices manufacturers are required to report within thirty

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[19] *See* 21 U.S.C. § 393(b) (The FDA shall "promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner."); *What Does FDA Regulate?*, FOOD AND DRUG ADMINISTRATION, http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194879.htm (last visited Aug. 27, 2010). *See also* ARTHUR N. LEVINE, FDA ENFORCEMENT MANUAL 3-4 (2006) ("The FDA regulates approximately 114,700 establishments engaged in manufacturing, processing, repacking, relabeling, and wholesale warehousing of foods, drugs, medical devices and cosmetics. The agency is responsible for monitoring the integrity of research submitted to it by approximately 25,000-30,000 clinical investigators.").

[20] *Products and Medical Procedures*, FOOD AND DRUG ADMINISTRATION, http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/default.htm (last visited Aug. 27, 2010).

days[21] any information suggesting that one of their products has "caused or contributed to a death or a serious injury" or has malfunctioned in a way that could have caused death or serious injury. 21 C.F.R. § 803.50(a). Reporting obligations are also imposed on user facilities, including hospitals, ambulatory surgical facilities, nursing homes, outpatient diagnostic facilities, and outpatient treatment facilities. *See* 21 C.F.R. §§ 803.30, 803.3.

As with the "reportability" standards for drugs, medical device reports are intentionally over-inclusive. *See, e.g.*, 21 C.F.R. § 803.16 (explaining that a medical device AER "is not necessarily an admission that the device . . . caused or contributed to the reportable event"). A manufacturer's obligation to report arises as long as the device "*may* have been a factor in the death or injury" and even if it is due to "[u]ser error." Medical Devices; Medical Device Reporting, 70 Fed. Reg. 9,516, 9,520 (Feb. 28, 2005) (emphasis added). In 2009 alone, the FDA received over 200,000 AERs from manufacturers, importers, distributors, and health care providers.[22]

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[21] The obligation arises as soon as "an employee of the entity . . . has acquired information that reasonably suggests a reportable adverse event has occurred." Medical Devices; Medical Device Reporting, 70 Fed. Reg. 9,516, 9,519 (Feb. 28, 2005). If the reportable event is one that requires remedial action, a report must be filed within five work days. *Id.* at 9,522.

[22] Manufacturer and User Facility Device Experience Database, FOOD AND DRUG ADMINISTRATION, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm127891.htm (last visited Aug. 27, 2010).

Manufacturers of dietary supplements, such as vitamins, or other products intended to "supplement the diet" containing a mineral, an herb or other botanical, or an amino acid,[23] are also subject to reporting requirements. 21 U.S.C. § 379aa-1(b)(1). Manufacturers, packers, and distributors of dietary supplements must forward "serious adverse event reports"[24] to the FDA, 21 U.S.C. § 379aa-1(b)(1), and keep records of any other AER received, 21 U.S.C. § 379aa-1(e)(1).

Again these reporting requirements are designed to be over-inclusive, and it is questionable how many reports are actually attributable to defects in the supplements involved. *See* Ashish R. Talati & Abhishek K. Gurnani, *Dietary Supplement Adverse Event Reports: Review and Analysis*, 64 FOOD & DRUG L.J. 503, 510-11 (2009) (noting large proportion of reports may be attributable to patients' "extensive medical histories and diseases," "age-related health problems," "the combination of dietary supplement products with other various medications," and failure to properly heed warnings

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[23] 21 U.S.C. § 321(ff).

[24] An "adverse event" is "any health-related event associated with the use of a dietary supplement that is adverse." 21 U.S.C. § 379aa-1(a)(1). A "serious adverse event" is an adverse event that either (1) results in death, a life-threatening experience, inpatient hospitalization, a persistent or significant disability or incapacity, a congenital anomaly or birth defect or (2) requires medical or surgical intervention to prevent such results. 21 U.S.C. § 379aa-1(a)(2). These definitions mirror those for drugs. *See* 21 U.S.C. § 379aa(a)(1) & (2).

on product labels). Thus, in *McClain v. Metabolife Intern., Inc.*, a products liability action involving an herbal weight-loss supplement, the Eleventh Circuit excluded expert testimony that was substantially based on adverse events reports submitted to the FDA. 401 F.3d 1233, 1236 (11th Cir. 2005).[25]

The potential unreliability of this information does not necessarily lessen its value for the FDA's regulatory efforts, as such reports are only one aspect of its broader regulatory strategy that includes analyzing information from such sources as "inspections of dietary supplement manufacturers and distributors . . . consumer and trade complaints . . . laboratory analyses of product samples, and monitor[ing of] retail outlets, including the Internet."[26]

When promulgating the dietary supplements rule, the FDA estimated that it would affect about 1,460 manufacturers. *See* Current Good

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[25] The court explained that the testimony was inadmissible because the expert's reliance on the reports demonstrated "more of a federal agency risk analysis approach . . . than a courtroom causation analysis" and because "he relied on data that lacks the indicia of scientific reliability"; the court also noted that "[u]ncontrolled anecdotal information [such as the AERs] offers one of the least reliable sources to justify opinions about both general and individual causation." *McClain*, 401 F.3d at 1236.

[26] *Oversight of Dietary Supplements: Hearing Before the S. Special Comm. of Aging* (statement of Joshua M. Sharfstein, Principal Deputy Commissioner, Food and Drug Administration), (May 26, 2010) http://www.fda.gov/NewsEvents/Testimony/ucm213531.htm.

Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements, 72 Fed. Reg. 34,752, 34,920 (June 25, 2007). A total of 1,107 reports were filed in 2008 and 1,275 in 2009.[27] These numbers are likely to rise: the reporting system only applies to supplements labeled on or after December 22, 2007; and the FDA allowed companies an initial two-year grace period before enforcing the requirements.[28]

Manufacturers of radiation-emitting products, which include, among other things, heavy-duty X-ray machines for hospitals and airports, microwave ovens, and laser light shows,[29] also have to report to the FDA whenever they have "reasonable grounds"[30]

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[27] *Id.*

[28] Talati & Gurnani, at 504 ("While the Act applies to all supplements labeled on or after December 22, 2007, FDA is allowing an additional two-year period for dietary supplement companies to comply with the new requirements. FDA intends to begin enforcing these requirements for dietary supplements labeled on or after January 1, 2010.").

[29] *Radiation-Emitting Products and Procedures*, FOOD AND DRUG ADMINISTRATION, http://www.fda.gov/RadiationEmittingProducts/RadiationEmittingProductsandProcedures/default.htm (last visited Aug. 27, 2010). *See also A-Z List of Regulated Products & Procedures*, FOOD AND DRUG ADMINISTRATION, http://www.fda.gov/RadiationEmittingProducts/RadiationEmittingProductsandProcedures/ucm135878.htm (last visited Aug. 27, 2010).

[30] "Reasonable grounds" include "professional, scientific, or medical facts or opinions documented or otherwise, that conclude or lead to the conclusion that such an incident has occurred." 21 C.F.R. § 1002.20(a).

for suspecting an "accidental radiation occurrence." 21 C.F.R. § 1002.20. Manufacturers are also required to report any product they "produced, assembled, or imported" that has a defect[31] or fails to comply with applicable federal standards. 21 C.F.R. § 1003.10. Since there is overlap between the definitions of medical devices and radiation-emitting products, some manufacturers are subject to reporting obligations under both regulatory schemes.[32] Once again, these reporting obligations arise *before* causation has been established or the occurrence of an incident has actually been confirmed. *See* 21 C.F.R. § 1002.20(a) (Manufacturers must report as soon as they have any "reasonable grounds for *suspecting* that an incident has occurred." (emphasis added)).

Veterinary medicines are also the subject of adverse event reports, which are to be made even if an incident does not appear to be "drug related" or the drug was not used "in accordance with the approved labeling." *See* 21 C.F.R. § 514.3; *see also* 21 C.F.R. § 514.80.[33] These reports may originate from

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[31] To be reportable, the defect should "relate[] to the safety of use of such product by reason of the emission of electronic product radiation." 21 U.S.C. § 360*ll*.

[32] *See Overlap of FDA Enforcement Authorities for Radiation-Emitting Products*, FOOD AND DRUG ADMINISTRATION, http://www.fda.gov/downloads/RadiationEmittingProducts/ElectronicProductRadiationControlProgram/LawsandRegulations/UCM133545.pdf (last visited Aug. 27, 2010).

[33] Adverse events may occur "in the course of the use of an animal drug product" or involve a failure of the product "to produce its expected pharmacological or clinical effect." 21

"anyone directly involved with the purported adverse event."[34]

Most food manufactures are required to file electronically with the recently-established Reportable Food Registry ("the Registry") within twenty-four hours of determining that an article of food has a "reasonable probability" of "caus[ing] serious adverse health consequences or death to humans or animals." 21 U.S.C. §§ 350f (a) and (d).[35] Approximately 161,000 domestic and 244,000 foreign facilities are subject to the Registry's jurisdiction

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C.F.R. § 514.3(1). The definition also includes adverse events "occurring in humans from exposure during manufacture, testing, handling, or use of a new animal drug." *Id.* § 514.3(3).

[34] CENTER FOR VETERINARY MEDICINE, PHARMACOVIGILANCE OF VETERINARY MEDICINAL PRODUCTS: MANAGEMENT OF ADVERSE EVENT REPORTS, HHS 8 (May 1, 2006), http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/ucm052657.pdf.

[35] The Registry is a tool the regulator uses to identify potential problems early on, not a means for the determination of causation or liability. *See, e.g.*, Report: A New Approach to Targeting Inspection Resources, 75 Fed. Reg. 44,793-01, 44,794 (July 30, 2010) (explaining that the Registry provides "early warning to [the] FDA about potential public health risks" and "increase[s] the speed with which the agency and its partners at the State and local levels can investigate the reports and take appropriate followup action"). Thus, "[a] report or notification . . . shall not be considered an admission that the article of food involved is adulterated or caused or contributed to a death, serious injury, or serious illness." 21 U.S.C. § 350f (j).

which covers products as diverse as dairy, seafood, baked goods, candy, eggs, frozen foods, seasoning, and sweeteners.[36]

Infant formula, while a subset of "food"[37] as defined by the regulation, is excluded from the Registry[38] and subject instead to independent reporting requirements. Manufacturers are required to "promptly notify" the FDA whenever they have knowledge that "reasonably supports the conclusion" that the formula "*may* not provide the nutrients required" or "*may* be otherwise adulterated or misbranded." 21 U.S.C. § 350a(e)(1) (emphasis added).

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[36] *See* A NEW APPROACH TO TARGETING INSPECTION RESOURCES AND IDENTIFYING PATTERNS OF ADULTERATION: THE REPORTABLE FOOD REGISTRY, FOOD AND DRUG ADMINISTRATION 9-10, 12 (July 28, 2010), *available at* http://www.fda.gov/downloads/Food/FoodSafety/FoodSafetyPrograms/RFR/UCM220280.pdf. The FDA's reporting requirements apply to "any facility engaged in manufacturing, processing, packing, or holding food for consumption in the United States." 21 U.S.C. § 350d(a). The definition of "facility" excludes farms, restaurants, other retail food establishments, nonprofit food establishments and fishing vessels. 21 U.S.C. § 350d(b)(1). The Registry also does not cover products under the exclusive jurisdiction of the Department of Agriculture. 75 Fed. Reg. at 44,973-01.

[37] Infant formula is defined as "a food which purports to be or is represented for special dietary use solely as a food for infants by reason of its simulation of human milk or its suitability as a complete or partial substitute for human milk." 21 U.S.C. § 321(z).

[38] *See* 21 U.S.C. § 350f(a)(2) (excluding infant formula from definition of "reportable food").

III. Implications of Ninth Circuit's Decision for Products Outside of the FDA's Jurisdiction

The potential impact of the Court's decision in this case goes beyond industries regulated by the FDA. Additional examples are provided by such products as motor vehicles, aircraft, and consumer products in general. All are subject to regimes that are designed to provide the regulator with an over-inclusive array of information about potential safety trends.[39]

1. Motor vehicles, such as passenger cars, trucks, motorcycles and buses, and motor vehicle equipment, such as tires and child restraint systems,[40] are regulated by the National Highway

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[39] These are just a sample of requirements related to federal agencies. Specific reporting requirements exist for many other products both at the federal and state level. *See, e.g.*, 46 U.S.C. § 4310 and 33 C.F.R. § 179 (requiring recreational vessel manufacturers to notify the Coast Guard of any "defect related to safety" in their vessels); Ga. Code Ann. § 26-2-27.1 (requiring "food processing plants"—defined as "commercial operation[s] that manufacture[] food for human consumption"—to report to the Georgia Department of Agriculture all food that contains "any poisonous or deleterious substance which may render it injurious to health").

[40] Motor vehicles include any vehicle "driven or drawn by mechanical power or manufactured primarily for use on public streets, roads, and highways" such as passenger cars, trucks, motorcycles and buses, while motor vehicle equipment includes "any system, part, or component of a motor vehicle as originally manufactured; . . . or sold for replacement or improvement . . . or as an accessory or addition to a motor vehicle; or, any device or an article or apparel . . . that is not a system, part, or component of a

Traffic Safety Administration ("NHTSA"). Manufacturers of these products are subject to a variety of reporting requirements, including those set forth in the Transportation Recall Enhancement, Accountability, and Documentation Act ("TREAD Act"), Pub. L. No. 106-414, 114 Stat. 1800 (2000).

Under the TREAD Act's "Early Warning" requirements, manufacturers are to report information related to "potential defects," and reports of injury or death related to their products, as well as other relevant data. With some variation depending on company size, manufacturers of vehicles, tires, and child restraint systems must submit quarterly reports on, *inter alia*, (1) every incident involving at least one death or injury identified in a claim against the manufacturer and alleged to have been caused by a possible defect in its vehicle and (2) the "[n]umbers of property damage claims, consumer complaints, warranty claims, and field reports" that they receive regarding their products. 49 C.F.R. § 579.21-27. NHTSA also collects and monitors vehicle owner complaints through its website.[41]

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motor vehicle and is manufactured, sold, delivered, offered, or intended to be used only to safeguard motor vehicles and highway users against risk of accident, injury, or death." 49 U.S.C. § 30102(a)(6)-(7).

[41] *Defects & Recalls: File a Safety Complaint*, OFFICE OF DEFECTS INVESTIGATION, http://www-odi.nhtsa.dot.gov/ivoq/index.cfm (last visited Aug. 27, 2010). *See also* Reporting of Information and Documents About Potential Defects, 67 Fed. Reg. 45,822, 45,823 (July 10, 2002) (explaining that the reports are intended to "help NHTSA

The reporting procedures established under the TREAD Act are designed to capture any information that "*may help* identify defects related to motor vehicle safety and noncompliances with Federal motor vehicle safety standards." 49 C.F.R. § 579.1 (emphasis added). The regulation is designed to capture information about "*possible* safety-related defects and noncompliances." *Id.* at § 579.2 (emphasis added). As explained by the NHTSA's Office of Defects Investigation:

> Manufacturers must report any claim against and received by the manufacturer. Claims are merely requests or demands for relief related to a crash, the failure of a component or system, or a fire originating in or from a vehicle. These claims are unverified allegations. They may help NHTSA identify a possible defect, but in and of themselves the claims are not evidence of a defect.[42]

In addition to the "Early Warning" reports, manufacturers of motor vehicles and certain motor vehicle equipment must report any defect that relates to motor vehicle safety to NHTSA within five days of determining that it exists. *See* 49 U.S.C. § 30118(c)(1); 49 C.F.R. § 573.6(b).

While these reports are essential to the agency's ability to fulfill its mission, many of them

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identify trends that could indicate potential safety problems").

[42] *Public Release of EWR Data*, OFFICE OF DEFECTS INVESTIGATION, (Sept. 10, 2008), http://www-odi.nhtsa.dot.gov/ewr/qb/documents/NHTSA-ODI-EWR-Facts.pdf.

have limited probative value for other purposes. Consumer complaints on their own, for example, are not generally sufficient to show that a vehicle was defective. *U.S. v. Gen. Motors Corp.*, 841 F.2d 400, 412-13 (D.C. Cir. 1988). Courts have also excluded vehicle owner complaints and accident reports as hearsay, as being irrelevant, or because their prejudicial effect far outweighs their minimal probative value. *See e.g., Jones v. Ford Motor Co.*, 204 Fed. App'x. 280, 286-87 (4th Cir. 2006); *Cole v. Gen. Motors*, No. 87-5966, 1988 WL 76522, at *7 (6th Cir. July 21, 1988).

2. The aviation industry is also subject to significant reporting requirements. The Federal Aviation Administration ("FAA") imposes requirements on certain manufacturers[43] to report aircraft[44] failures, malfunctions and defects it determines have resulted in one of an enumerated list of occurrences, including exhaust or brake system failure, engine failure, abnormal vibration or buffeting, fire or flammable fluid leakage. 14 C.F.R. § 21.3(a) & (c).

Similarly, operators of airplanes with a seating configuration of twenty or more passengers

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[43] Reporting requirements are imposed on manufacturers who hold a Type Certificate (including a Supplemental Type Certificate), a Parts Manufacturer Approval, a Technical Standard Orders authorization, or the licensee of a Type of Certificate. 14 C.F.R. § 21.3(a); *see also* 14 C.F.R. §§ 21.113; 21.21-29; 21.303; 21.601.

[44] "Aircraft" is defined as "a device that is used or intended to be used for flight in the air," and includes airplanes and rotorcrafts. 14 C.F.R. § 1.1.

or a maximum payload capacity of 6,000 pounds must file a "service difficulty report" on "the occurrence or detection of each failure, malfunction, or defect." 14 C.F.R. § 125.409(a).[45] Air carriers and operators are also required to file "service difficulty reports" concerning seventeen enumerated types of failures, malfunctions and defects, including fires during flight, false fire warning during flight and damage caused during flight by the engine exhaust system. 14 C.F.R. § 121.703. The FAA collects these reports to track repair problems with private, commercial and military aircraft and aircraft components. The reports are largely made by the aircraft owners and thousands are filed every month. These reports are loaded on a publicly accessible database.[46] A query of the database reveals that more than a thousand such reports were filed just for the first week of January 2010. Manufacturers have the ability to view these reports, and the FAA uses the reports to publish monthly *Aviation Maintenance Alerts*.[47]

In addition, certificated domestic aviation repair stations—which are repair stations certified

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[45] "Each report of occurrences during a 24-hour period shall be submitted to the collection point within the next 96 hours." 14 C.F.R § 125.409(b).

[46] *See Service Difficulty Reporting Site*, FEDERAL AVIATION ADMINISTRATION, http://av-info.faa.gov/sdrx/Query.aspx (last visited Aug. 27, 2010).

[47] *Aviation Maintenance Alerts*, FEDERAL AVIATION ADMINISTRATION, http://www.faa.gov/aircraft/safety/alerts/aviation_maintenance (last visited Aug. 27, 2010).

by the FAA according to procedures laid out in 14 C.F.R. § 145.51—are required to report within ninety-six hours from the time of discovery, any serious failure, malfunction, or defect they discover in an aircraft component. 14 C.F.R. § 145.221(a). The regulations outline the information that the service difficulty report should provide, including the defective article, the nature of the defect, and the defect's apparent cause. 14 C.F.R. § 145.221(b).

While these reports assist the agency in fulfilling its mission, they have limited probative value for other purposes. For example, the reports are based largely on witness accounts and other hearsay which courts ordinarily exclude from trial. *See generally In re Cessna 208 Series Aircraft Prod. Liab. Litig.*, MDL No. 1721, 2009 WL 2780223 (D. Kan. Sept. 1, 2009) (holding that an FAA Notice of Proposed Rulemaking, which was based largely upon reports of witnesses and other hearsay, was inadmissible under Fed. R. Evid 403, because it was not issued to determine the "legal liability of a particular party or the mechanical soundness of a particular airplane model").

3. Manufacturers of thousands of consumer products are subject to reporting obligations under the Consumer Product Safety Act, which charges the United States Consumer Product Safety Commission ("CPSC") with the task of protecting the public against "unreasonable risks of injury associated with consumer products." Consumer Product Safety Act ("CPSA"), Pub. L. No. 92-573, § 2(a), 86 Stat. 1207, 1207 (1972). The CPSC has jurisdiction over

approximately 15,000 types of consumer products.[18] The CPSA "gave the Commission broad powers to gather, analyze, and disseminate vast amounts of private information." *Consumer Prod. Safety Comm'n v. GTE Sylvania, Inc.*, 447 U.S. 102, 111, (1980) ("'If the Commission is to act responsibly and with adequate basis, it must have complete and full access to information relevant to its statutory responsibilities. Accordingly, the committee has built into this bill broad information-gathering powers.'" (quoting H.R. Rep. No.92-1153, at 31 (1972)).

Manufacturers must report "a broad spectrum of safety related information" to the CPSC. 16 C.F.R.

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[18] The Consumer Product Safety Act defines "consumer product" as:

> [A]ny article, or component part thereof, produced or distributed (i) for sale to a consumer for use in or around a permanent or temporary household or residence, a school, in recreation, or otherwise, or (ii) for the personal use, consumption or enjoyment of a consumer in or around a permanent or temporary household or residence, a school, in recreation, or otherwise.

15 U.S.C. § 2052(a)(5). Courts have held that this definition should be "liberally construed" in furtherance of "the protection of consumers from injury due to unsafe products." *U.S. v. One Hazardous Prod. Consisting of a Refuse Bin*, 487 F. Supp. 581, 584 (D.N.J. 1980) (citing *Consumer Prod. Safety Comm'n v. Chance Mfg. Co.*, 441 F. Supp. 228, 231-34 (D.D.C. 1977)). *See also Who We Are - What We Do*, CONSUMER PRODUCT SAFETY COMMISSION, http://www.cpsc.gov/cpscpub/whoweare.html (last visited Aug. 23, 2010) (describing scope of agency's jurisdiction).

§ 1115.2(b).[49] They must report all failures to comply with applicable rules and regulations. 15 U.S.C. § 2064(b)(1)-(2). They must file reports of all products that contain defects,[50] which "could create a substantial product hazard," 15 U.S.C. § 2064(b)(3), and all products that "create[] an unreasonable risk of serious injury or death." 15 U.S.C. § 2064(b)(4). They must also report whenever a product is subject to three or more civil actions in a two-year period that result in settlement or judgment in favor of a plaintiff. 15 U.S.C. § 2084(a); 16 C.F.R. § 1116.3(d).[51] Manufacturers of marbles, small balls, latex balloons, and games and toys containing small parts are subject to additional requirements under the Child Safety Protection Act to report all choking incidents. Pub. L. No. 103-267, 108 Stat. 722 (1994). *See also* 16 C.F.R. § 1117.

As the statutes and regulations show, these reports are meant to be over-inclusive. For example, firms are not supposed to "await complete or

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[49] These reporting obligations also apply to manufacturers regulated under the Refrigerator Safety Act, the Flammable Fabrics Act, the Federal Hazardous Substances Act and the Poison Prevention Packaging Act. 16 C.F.R. § 1115.2(d); *see also* 15 U.S.C. § 2051, *et seq.*

[50] "Defects" include "[a]t a minimum . . . the dictionary or commonly accepted meaning of the word. Thus, a defect is a fault, flaw, or irregularity that causes weakness, failure or inadequacy in form or function." 16 C.F.R. § 1115.4.

[51] "The manufacturer's opinion as to the validity of the allegation is irrelevant." 16 C.F.R. § 1116.7(b), but manufacturers "may specifically deny that the information [submitted] reasonably supports [liability]." *Id.*

accurate risk estimates before reporting," 16 C.F.R. § 1115.14(c), but instead to err on the side of reporting. 16 C.F.R. § 1115.4(e) ("[S]ubject firms are *urged to report if in doubt* as to whether a defect could present a substantial product hazard."). The obligation to report arises as soon as the manufacturer "receive[s] the first information regarding a potential hazard, noncompliance or risk," 16 C.F.R. § 1115.12(a), and reporting should not be delayed "in order to determine to a certainty" the existence of a problem. *Id.* The obligation to report applies "even when no final determination of the risk is possible." 16 C.F.R. § 1115.6(a). In the case of choking hazards, manufacturer "*must not wait* until they have investigated the incident or conclusively resolved whether the information is accurate or whether their product was involved in the incident." 16 C.F.R. § 1117.3. Rather the existence of an "allegation . . . is sufficient to require a report." *Id.*

The CPSC recognizes that these reports have limited value in terms of establishing causation. The regulations specifically state that the filing of a report "does not automatically indicate the presence of a substantial product hazard," 16 C.F.R. § 1115.2(c), and that the reports "shall not be interpreted, for any purpose, as an admission of liability or of the truth of the information contained [therein]." 16 C.F.R. § 1117.8. Congress expressly recognized that reporting requirements are not equivalent to liability and should not be used "as the basis for criminal prosecution of the reporting person . . . except for offenses which require a showing of intent to defraud or mislead." 15 U.S.C. § 2064(b).

These reports are, instead, part of the CPSC's broader regulatory mandate and are designed to serve at most as initial indicators of a potential problem. The CPSC, for example, encourages consumers themselves to file reports and sets no threshold for such reporting.[52] It receives over 10,000 reports a year from consumers and industry, which it analyzes in order to "identify patterns of injuries and hazards associated with particular products."[53]

CONCLUSION

The Ninth Circuit's treatment of AERs provides no meaningful guidance to manufacturers and will result in investors receiving "essentially useless" information, not only as to over-the-counter cold medications, but across a wide range of industries. The appropriate standard is that of statistical significance adopted by the First, Second, and Third Circuits, and urged by Petitioners.

For the foregoing reasons, this Court should reverse the decision of the Ninth Circuit.

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[52] *See e.g.*, *Frequently Asked Questions*, CONSUMER PRODUCT SAFETY COMMISSION, http://www.cpsc.gov/about/faq.html (last visited Aug. 27, 2010) (explaining that the CPSC "welcomes" reports from consumers who "believe a product is unsafe").

[53] *Id.*

Respectfully submitted,

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August 27, 2010

APPENDIX A

Corporate Members of the
Product Liability Advisory Council
as of 8/24/2010

3M
A.O. Smith Corporation
ACCO Brands Corporation
Altec Industries
Altria Client Services Inc.
Anheuser-Busch Companies
Arai Helmet, Ltd.
Astec Industries
Bayer Corporation
Beretta U.S.A Corp.
BIC Corporation
Biro Manufacturing Company, Inc.
BMW of North America, LLC
Boeing Company
Bombardier Recreational Products
BP America Inc.
Bridgestone Americas Holding, Inc.
Brown-Forman Corporation
Caterpillar Inc.
Chrysler LLC
Continental Tire the Americas LLC
Crown Equipment Corporation
Daimler Trucks North America LLC
The Dow Chemical Company
E.I. duPont de Nemours and Company
Eli Lilly and Company
Emerson Electric Co.
Engineered Controls International, Inc.
Estee Lauder Companies

Exxon Mobil Corporation
Ford Motor Company
General Electric Company
General Motors Corporation
GlaxoSmithKline
The Goodyear Tire & Rubber Company
Great Dane Limited Partnership
Harley-Davidson Motor Company
Hawker Beechcraft Corporation
The Heil Company
Honda North America, Inc.
Hyundai Motor America
Illinois Tool Works, Inc.
International Truck and Engine Corporation
Isuzu Motors America, Inc.
Jaguar Land Rover North America, LLC
Jarden Corporation
Johnson & Johnson
Joy Global Inc., Joy Mining Machinery
Kawasaki Motors Corp., U.S.A.
Kia Motors America, Inc.
Kolcraft Enterprises, Inc.
Kraft Foods North America, Inc.
Leviton Manufacturing Co., Inc.
Lincoln Electric Company
Magna International Inc.
Marucci Sports, L.L.C.
Mazak Corporation
Mazda (North America), Inc.
Medtronic, Inc.
Merck & Co., Inc.
Microsoft Corporation
Mitsubishi Motors North America, Inc.
Mueller Water Products

Nintendo of America, Inc.
Niro Inc.
Nissan North America, Inc.
Novartis Pharmaceuticals Corporation
PACCAR Inc.
Panasonic
Pella Corporation
Pfizer Inc.
Porsche Cars North America, Inc.
Purdue Pharma L.P.
Remington Arms Company, Inc.
RJ Reynolds Tobacco Company
Schindler Elevator Corporation
SCM Group USA Inc.
Segway Inc.
Shell Oil Company
The Sherwin-Williams Company
Smith & Nephew, Inc.
St. Jude Medical, Inc.
Stanley Black & Decker, Inc.
Subaru of America, Inc.
Synthes (U.S.A.)
Techtronic Industries North America, Inc.
Terex Corporation
TK Holdings Inc.
The Toro Company
Toshiba America Incorporated
Toyota Motor Sales, USA, Inc.
Vermeer Manufacturing Company
The Viking Corporation
Volkswagen of America, Inc.
Volvo Cars of North America, Inc.
Vulcan Materials Company
Watts Water Technologies, Inc.

Whirlpool Corporation
Yamaha Motor Corporation, U.S.A.
Yokohama Tire Corporation
Zimmer, Inc.

AMICUS CURIAE BRIEF

Supreme Court, U.S.
FILED
AUG 27 2010
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No. 09-1156

In the Supreme Court of the United States

MATRIXX INITIATIVES, INC., *ET AL.*,
Petitioners,

v.

JAMES SIRACUSANO AND NECA-IBEW PENSION FUND,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

BRIEF OF THE SECURITIES INDUSTRY AND FINANCIAL MARKETS ASSOCIATION AND THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA AS *AMICI CURIAE* IN SUPPORT OF PETITIONERS SEEKING REVERSAL

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INTEREST OF *AMICI CURIAE*[1]

The Securities Industry and Financial Markets Association ("SIFMA") is a securities industry trade association that brings together the shared interests of hundreds of securities firms, banks, and asset managers. SIFMA's mission is to support a strong financial industry, investor opportunity, capital formation, job creation, and economic growth, while building trust and confidence in the financial markets. SIFMA, with offices in New York and Washington, DC, is the United States of America regional member of the Global Financial Markets Association.

The Chamber of Commerce of the United States of America (the "Chamber") is the world's largest business federation. The Chamber directly represents 300,000 members and indirectly represents the interests of an underlying membership of 3,000,000 companies and professional organizations of every size, in every industry sector, and from every region of the country. Chamber members transact business throughout the United States and a large number of countries around the world. An important

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[1] Pursuant to Rule 37.6 of the Rules of this Court, the undersigned hereby state that no counsel for a party authored any part of this brief, that no party or counsel for a party made a monetary contribution intended to fund the preparation or submission of this brief, and that no person or entity other than *amici curiae*, their members, or their counsel has made a monetary contribution to the preparation or submission of this brief. Pursuant to Rule 37.3(a) of the Rules of this Court, letters of consent from all parties to the filing of this brief are on file or have been submitted to the Clerk of the Court.

function of the Chamber is to represent the interests of its members in matters before Congress, the Executive Branch, and the courts.

SIFMA and the Chamber regularly file *amicus curiae* briefs in cases such as this that raise issues of vital concern to the participants in the securities industry and the nation's business community at large. Both have appeared before this Court as *amici curiae*, jointly or separately, in several cases involving issues arising under the federal securities laws, most recently *Morrison v. National Australia Bank, Ltd.*, 130 S. Ct. 2869 (2010) (extraterritorial application of anti-fraud provisions of federal securities laws), *Merck & Co., Inc. v. Reynolds*, 130 S. Ct. 1784 (2010) (statute of limitations for bringing private securities fraud claim), and *Jones v. Harris Associates L.P.*, 130 S. Ct. 1418 (2010) (breach of fiduciary duty under the Investment Company Act of 1940).

Amici submit this brief in support of Petitioners, Matrixx Initiatives, Inc., *et al.* ("Defendants"), in their petition seeking reversal of the decision of the United States Court of Appeals for the Ninth Circuit reversing the district court's dismissal of the complaint filed against them by Respondents James Siracusano and NECA-IBEW Pension Fund ("Plaintiffs"). *Amici* are concerned that the Ninth Circuit's decision, if upheld by this Court, will magnify the exposure of market participants to liability under the federal securities laws by leaving them with little or no guidance as to what disclosures are required under those laws and by opening the floodgates to mischievous strike suits.

SUMMARY OF THE ARGUMENT

The Ninth Circuit's decision applied the incorrect legal standard to Plaintiffs' allegations of materiality and improperly rejected the District Court's use of a general standard to evaluate the issue of whether Plaintiffs had sufficiently pled materiality.

First, the Ninth Circuit, in evaluating the sufficiency of Plaintiffs' materiality allegations, improperly applied the "notice pleading" standard embodied by Federal Rule of Civil Procedure 8. Materiality is an essential "circumstance" of the alleged securities fraud. As a result, materiality, like all other elements of a securities fraud, is subject to the heightened pleading standard of Federal Rule of Civil Procedure 9(b) and must be pled with particularity.

Second, the Ninth Circuit embraced the misguided view that materiality is almost always a matter for a jury to decide. Courts may appropriately address materiality on a motion to dismiss because, at that stage of the case, the well-pleaded allegations assessed by the judge are uncontroverted and accepted as true, and the judge therefore does not encroach upon the jury's role to weigh the evidence.

Finally, based on its misguided views about the propriety of addressing materiality at the pleading stage of a case, the Ninth Circuit wrongly rejected the district court's use of a "statistical significance" standard to evaluate whether Plaintiffs had sufficiently pled materiality. Materiality standards are not barred by this Court's holding in *Basic, Inc. v. Levinson*, 485 U.S. 224 (1988), and are widely

and properly applied by the federal circuits in evaluating the adequacy of materiality allegations in federal securities fraud cases.

For the foregoing reasons, *Amici* urge this Court to reverse the Ninth Circuit's decision.

ARGUMENT

To establish a securities fraud claim based on fraudulent statements, a plaintiff must plead and prove a misstatement or omission of a *material* fact. *Basic*, 485 U.S. at 238. "It is not enough that a statement is false or incomplete, if the misrepresented fact is otherwise insignificant." *Id.*; *see also Greenhouse v. MCG Capital Corp.*, 392 F.3d 650, 656 (4th Cir. 2004) ("The plain language of Rule 10b-5 . . . requires any successful securities fraud suit to allege a fact that is both untrue *and* material."). A fact is material when there is "'a substantial likelihood'" that a reasonable investor would view it as "'significantly alter[ing] the "total mix" of information made available.'" *Basic*, 485 U.S. at 231-32 (quoting *TSC Indus., Inc. v. Northway, Inc.*, 426 U.S. 438, 449 (1976)).

The materiality requirement serves important public policy purposes, both for investors and for other market participants. Investors benefit from a standard that "filter[s] out essentially useless information that a reasonable investor would not consider significant," *Basic*, 485 U.S. at 234, and that prevents corporations from "bury[ing] the shareholders in an avalanche of trivial information – a result that is hardly conducive to informed decisionmaking," *TSC Indus.*, 426 U.S. at 448-49. Issuers, financial intermediaries and other market participants, on the other hand, can take comfort in

the fact that this Court has established an objective materiality standard that treats "a 'reasonable investor' [a]s neither an ostrich, hiding her head in the sand from relevant information, nor a child, unable to understand the facts and risks of investing." *Greenhouse*, 392 F.3d at 656. Accordingly, securities defendants expect that courts will dismiss securities fraud actions that do not adequately plead materiality – either because the plaintiffs have failed to explain how the allegedly false facts were material or because the allegedly false facts are immaterial as a matter of law.

In light of this legal and public-policy background, the Ninth Circuit's approach to assessing Plaintiffs' materiality allegations was fundamentally flawed. As described below, in a securities fraud case, plaintiffs must plead this element of their claim with particularity. The Ninth Circuit never analyzed whether Plaintiffs' materiality allegations met this standard. Moreover, contrary to the Ninth Circuit's decision, the issue of materiality is appropriately addressed at the pleading stage of a case, and courts frequently and properly apply materiality standards in determining whether materiality has been adequately pled as a matter of law.

I. Materiality Is an Element of a Fraud Claim and Must Be Pled with Particularity.[2]

In evaluating Plaintiffs' materiality allegations, the Ninth Circuit applied the "notice pleading" standard embodied in Federal Rule of Civil Procedure 8 ("Rule 8"). To determine the sufficiency of a complaint's materiality allegations under Rule 8 for purposes of a motion to dismiss, a court need examine only whether the complaint fails to "'state a claim to relief that is plausible on its face.'" *See Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009) (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). This was an error. In fact, the Ninth Circuit should have evaluated Plaintiffs' materiality allegations subject to the heightened pleading standard found in Federal Rule of Civil Procedure 9(b) ("Rule 9(b)").

Rule 9(b) requires a plaintiff to "state with particularity the circumstances constituting fraud." Claims under Section 10(b) of the Securities Exchange Act necessarily sound in fraud. *See Chiarella v. United States*, 445 U.S. 222, 234-35 (1980) (Section 10(b) catches fraud). Moreover, this Court has emphasized that materiality is an element and an essential "circumstance" of a Section 10(b) and Rule 10b-5 securities fraud claim. *Basic*, 485 U.S. at 232. "[A] plaintiff must show that the statements were *misleading* as to a

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[2] Petitioners argued before the Ninth Circuit that Respondents had failed to "allege sufficiently particularized facts" demonstrating materiality. *See* Brief of Defendants-Appellees, *Siracusano v. Matrixx Initiatives, Inc.*, 585 F.3d 1167 (9th Cir. 2009) (No. 06-15677), 2006 WL 3380679 at *11.

material fact. It is not enough that a statement is false or incomplete, if the misrepresented fact is otherwise insignificant." *Id.* at 238. *See also Neder v. United States*, 527 U.S. 1, 21-23 (1999) (materiality is an element of fraud).

While no circuit court has specifically addressed whether Rule 9(b) applies to the pleading of materiality, a number of courts have held in general terms that Rule 9(b) applies to *all* elements of a federal securities fraud claim. *See, e.g., Thompson v. Relationserve Media, Inc.*, 610 F.3d 628, 633 (11th Cir. 2010) ("Because Rule 10b-5 sounds in fraud, the plaintiff must plead the elements of its violation with particularity."); *Adams v. Kinder-Morgan, Inc.*, 340 F.3d 1083, 1095 (10th Cir. 2003) (Rule 9(b) applies to "the elements of a securities fraud claim").[3] Moreover, courts specifically have found that Rule 9(b) applies to analogous elements of a Section 10(b) claim, including loss causation and reliance. The Fourth Circuit has observed that "[a] strong case can be made that because loss causation is among the circumstances constituting fraud for which Rule 9(b) requires particularity, loss causation should be pleaded with particularity." *Teachers' Ret. Sys. of La. v. Hunter*, 477 F.3d 162, 185-86 (4th Cir. 2007). The same "strong case" exists for materiality. Similarly, and even more definitively, the Eighth Circuit has held that plaintiffs must "plead reliance in accordance with the specificity requirements of

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[3] The pleading standard for the element of scienter (i.e., fraudulent intent), is addressed separately in the Private Securities Litigation Reform Act of 1995, which creates a "strong inference" requirement. 15 U.S.C. § 78u-4(b)(2).

Federal Rule 9(b)." *In re NationsMart Corp. Secs. Litg.*, 130 F.3d 309, 321 (8th Cir. 1997). Accordingly, the Ninth Circuit should have examined Plaintiffs' pleading of materiality subject to Rule 9(b)'s particularity requirement.

The proper choice of pleading standards is important. Among other functions, Rule 9(b)'s heightened pleading standard serves to weed out meritless fraud claims. *See Kearns v. Ford Motor Co.*, 567 F.3d 1120, 1125 (9th Cir. 2009) (Rule 9(b) serves to prohibit plaintiffs from "unilaterally imposing upon the court, the parties and society enormous social and economic costs absent some factual basis") (internal quotation marks omitted); *United States ex rel. Williams v. Martin-Baker Aircraft Co.*, 389 F.3d 1251, 1256 (D.C. Cir. 2004) (Rule 9(b) "discourages the initiation of suits brought solely for their nuisance value, and safeguards potential defendants from frivolous accusations of moral turpitude") (internal quotation marks omitted). Pursuant to Rule 9(b), Plaintiffs must "explain why the statements were fraudulent," *Rombach v. Chang*, 355 F.3d 164, 170 (2d Cir. 2004) (quoting *Mills v. Polar Molecular Corp.*, 12 F.3d 1170, 1175 (2d Cir. 1993)), by alleging "the who, what, when, where and how: the first paragraph of a newspaper story." *Garfield v. NDC Health Corp.*, 466 F.3d 1255, 1262 (11th Cir. 2006) (internal quotation marks omitted). As to materiality, the complaint should include details from which a judge could infer that the alleged misstatement or omission involved a fact that a reasonable investor would have considered important. *See Cal. Pub. Emps.' Ret. Sys. v. Chubb Corp.*, 394 F.3d 126, 144 (3d Cir. 2004) (Rule 9(b)

requires plaintiffs to "inject[] precision and some measure of substantiation into their allegations of fraud"). And the complaint should be dismissed if it does not do so. *Id.* (Rule 9(b) is "rigorously applied in securities fraud cases"). In this case, the Ninth Circuit never conducted the required Rule 9(b) particularity analysis.

II. Materiality Is Appropriately Addressed on a Motion to Dismiss.

The pleading of materiality with particularity is a threshold requirement for overcoming a motion to dismiss. Moreover, it is necessary because, contrary to the Ninth Circuit's position, it is appropriate for a court to determine whether materiality exists as a matter of law at the pleading stage of a case. On a motion to dismiss, the facts are not in dispute and there can be no suggestion that a court is usurping the proper role of the trier of fact in making this determination.

The Ninth Circuit found that "[q]uestions of materiality . . . involv[e] assessments peculiarly within the province of the trier of fact" and that, as a result, materiality rarely can be addressed at the pleading stage of a case. *Siracusano v. Matrixx Initiatives, Inc.*, 585 F.3d 1167, 1178 (9th Cir. 2009) (internal quotation marks and citations omitted). The court's insistence that materiality should not be evaluated on a motion to dismiss, however, is based on an incorrect reading of this Court's precedent.

In *TSC Industries*, 426 U.S. 438, and *Basic*, 485 U.S. 224, this Court reviewed grants of summary judgment against the plaintiffs. In both cases, the lower courts had decided the issue of materiality

based on the evidence. In addressing the question of whether materiality could be decided on *summary judgment*, this Court explained that "[t]he determination [of materiality] requires delicate assessments of the inferences a 'reasonable shareholder' would draw from a given set of facts and the significance of those inferences to him" – effectively warning that judges themselves should not ordinarily evaluate the evidence and decide the issue of materiality. *Basic*, 485 U.S. at 236 (citing *TSC Indus.*, 426 U.S. at 450).

Based on these *summary judgment* decisions, a number of courts, including the Ninth Circuit in this case, have held *at the pleading stage* that materiality is almost always a matter for a jury to decide. *See, e.g., Miss. Pub. Emps.' Ret. Sys. v. Boston Scientific Corp.*, 523 F.3d 75, 87 (1st Cir. 2008) ("The existence of a material omission is usually a question for the trier of fact."); *Oxford Asset Mgmt., Ltd. v. Jaharis*, 297 F.3d 1182, 1189 (11th Cir. 2002) ("The trier of fact usually decides the issue of materiality."). That view is misguided, however, because neither *TSC Industries* nor *Basic* addressed the issue of materiality within the context of *the pleadings*.[4]

Deciding whether a plaintiff has adequately pled materiality for purposes of a motion to dismiss

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[4] The Fourth Circuit has expressed some healthy skepticism about why lower courts have misapplied these decisions. As noted in its *Greenhouse* decision: "When courts decide they wish for a jury to hear a claim, they generally take pains to emphasize the fact-specificness of materiality. . . . No shortage of cases, however, make clear that materiality may be resolved by a court as a matter of law." 392 F.3d at 657.

does not run afoul of this Court's guidance in *TSC Industries* and *Basic*. A motion to dismiss involves an assessment of the plaintiff's well-pleaded allegations – which necessarily are uncontroverted at that stage of the case – not of the evidence. *See Alternative Sys. Concepts, Inc. v. Synopsys, Inc.*, 374 F.3d 23, 26 (1st Cir. 2004) (explaining that a motion to dismiss is decided on the averments in the complaint, but a motion for summary judgment is decided on evidence); *Bell v. Fur Breeders Agric. Coop.*, 348 F.3d 1224, 1230 (10th Cir. 2003) (a court must "consider the conduct alleged in the complaint in deciding a motion to dismiss, while it must look beyond the pleadings to the evidence before it when deciding a motion for summary judgment"). Indeed, judgments on the pleadings cannot involve the "delicate assessments" to which this Court referred in *TSC Industries* and *Basic*. On a motion to dismiss, reasonable inferences are drawn in favor of the plaintiff. *See Makor Issues & Rights, Ltd. v. Tellabs, Inc.*, 513 F.3d 702, 705 (7th Cir. 2008) (on motion to dismiss, "the court must treat the pleaded facts as true and draw all reasonable inferences in favor of the plaintiff") (internal quotation marks omitted).

Accordingly, where the (alleged) facts regarding an issue are unchallenged – as they are on a motion to dismiss, where the court must accept all well-pled factual allegations as true – a decision on materiality as a matter of law is appropriate. *See, e.g., Leadsinger, Inc. v. BMG Music Publ'g*, 512 F.3d 522, 530 (9th Cir. 2008) (mixed question of law and fact "may be considered on a motion to dismiss, which requires the court to consider all allegations as true"). A court therefore may decide at the

pleading stage whether "no reasonable jury could find it substantially likely that a reasonable investor would find the fact at issue material in the 'total mix' of information." *Greenhouse*, 392 F.3d at 657 (rejecting plaintiffs' argument that only a jury could decide issue of materiality at pleading stage); *see also Kapps v. Torch Offshore, Inc.*, 379 F.3d 207, 216 (5th Cir. 2004) ("Appellants claim that materiality should be a question of fact for the jury, but many Section 11 cases have been properly dismissed on the pleadings for lack of materiality."); *ABC Arbitrage Plaintiffs' Group v. Tchuruk*, 291 F.3d 336, 359 (5th Cir. 2002) ("[A] court can determine statements to be immaterial as a matter of law on a motion to dismiss.").

III. The Ninth Circuit Improperly Rejected the District Court's Use of a General Standard to Evaluate the Issue of Materiality as a Matter of Law.

Based on its erroneous determination that materiality decisions must be left to the trier of fact, the Ninth Circuit rejected the use of any general standards to evaluate whether an allegedly misrepresented fact is immaterial as a matter of law. *Siracusano*, 585 F.3d at 1178. The *Basic* decision, however, permits the use of materiality standards – the only issue is what *kind* of standard.

A fact is material for purposes of a federal securities fraud claim where there is "'a substantial likelihood'" that its disclosure "'would have been viewed by the reasonable investor as having significantly altered the "total mix" of information made available.'" *Basic*, 485 U.S. at 231-32

(quoting *TSC Indus.*, 426 U.S. at 449). In *Basic*, the Court applied that principle to reject a proposed standard that refused to find material all pre-merger negotiations "not yet at the agreement-in-principle stage." 485 U.S. 233-36. As the Court explained, such a proposed standard would "artificially exclud[e] from the definition of materiality information . . . which would otherwise be considered significant to the trading decision of a reasonable investor." *Id.* at 236.

As Defendants persuasively argue in their opening brief, the statistical significance standard at issue in this case does not present the problem that concerned the Court in *Basic*.

> [F]ar from "artificially excluding" otherwise relevant information, the statistical significance standard *defines* the information a reasonable investor would consider relevant, i.e., information that may indicate that the company product can cause an adverse event, thereby potentially exposing the company to financial losses. And it works to "filter out essentially useless information," namely, [adverse-event reports] reporting events that cannot be distinguished from background incident rates of that event. [*Basic*, 485] at 234. Filtering out this type of information is precisely "[t]he role of the materiality requirement." *Id.*

Pet'rs' Br. at 43-44.

Moreover, the Ninth Circuit's blanket rejection of the use of materiality standards in determining whether an allegedly misrepresented fact is

material as a matter of law threatens to undermine a wealth of well-established precedent. A number of materiality standards – all of which seek to properly define the information a reasonable investor would consider relevant – feature prominently within the federal securities fraud jurisprudence. For example, courts have held that the following categories of allegedly misrepresented facts are immaterial as a matter of law: (1) soft, "puffing" statements and vague, optimistic statements that lack specificity, *see, e.g.*, *ECA & Local 134 IBEW Joint Pension Trust of Chicago v. JP Morgan Chase Co.*, 553 F.3d 187, 206 (2d Cir. 2009); (2) predictions of future business prospects not worded as guarantees, *see, e.g.*, *Raab v. Gen. Physics Corp.*, 4 F.3d 286, 289-91 (4th Cir. 1993); and (3) factual omissions that do not affect stock price when disclosed, *see, e.g.*, *Oran v. Stafford*, 226 F.3d 275, 282 (3d Cir. 2000) (Alito, J.) These materiality standards are judicial determinations that for certain categories of facts "no reasonable jury could find it substantially likely that a reasonable investor would find the fact at issue material." *Greenhouse*, 392 F.3d at 657.

Along with their jurisprudential benefits, concrete and discernible materiality standards give clear guidance to public companies regarding the disclosures that can lead to securities fraud liability, thereby reducing the number of statements that can trigger the filing of claims. Materiality standards also promote consistency across the federal circuits and lend predictability to the outcome of securities fraud lawsuits. These materiality standards should remain undisturbed by the Court's decision in this case.

IV. Dismissing Cases That Cannot Establish Materiality Deters Meritless Securities Fraud Actions.

The use of Rule 9(b)'s heightened pleading requirement and materiality standards to eliminate meritless claims at the earliest stage in the litigation is particularly important in light of the unique vulnerability of issuers, financial intermediaries and other market participants to the deleterious effects of abusive private securities litigation. Over 35 years ago, the Court acknowledged that the *in terrorem* threat of costly litigation gives significant settlement value to even the most groundless securities fraud claims. *See Blue Chip Stamps v. Manor Drug Stores*, 421 U.S. 723, 740-41 (1975). To curtail the filing of meritless claims, courts rigorously apply Rule 9(b)'s heightened pleading standard. *See, e.g., Lentell v. Merrill Lynch & Co., Inc.*, 396 F.3d 161, 168 (2d Cir. 2005) ("[Rule 9(b)] is applied assiduously to securities fraud.").

In 1995, Congress responded to the problem of strike suits by passing the Private Securities Litigation Reform Act of 1995 ("Reform Act"), whose purpose was to suppress abuses in securities class-action litigation, including: (1) the routine filing of lawsuits against issuers of securities in response to any significant change in stock price, regardless of defendants' culpability, (2) the targeting of "deep pocket" defendants regardless of their culpability, and (3) the abuse of the discovery process to coerce settlements. *See* H.R. Conf. Rep. No. 104-369, at 31 (1995), *reprinted in* 1995 U.S.C.C.A.N. 730, 730. The Reform Act significantly increased a securities fraud plaintiff's

burden beyond Rule 9(b)'s mandate by requiring him to plead his claim, especially as to scienter, "with an unprecedented degree of specificity and detail." *Eminence Capital, LLC v. Aspeon, Inc.*, 316 F.3d 1048, 1052 (9th Cir. 2003).

Just a few years after the passage of the Reform Act, Congress spoke again on the issue of frivolous securities lawsuits with the passage of the Securities Litigation Uniform Standards Act of 1998 ("SLUSA"), which was designed to prevent plaintiffs from sidestepping the Reform Act's rigorous pleading requirements by filing securities class actions in state courts. *See Merrill Lynch, Pierce, Fenner & Smith, Inc.* v. *Dabit*, 547 U.S. 71, 82 (2006) (Congress enacted SLUSA to "prevent certain State private securities class action lawsuits alleging fraud from being used to frustrate the objectives of the Reform Act") (internal quotation marks omitted).

Despite these judicial and legislative efforts, the problem of abusive securities fraud litigation and coerced settlements still exists. The filing of securities class actions has continued apace, with an average of 242 new cases being filed every year. *See* Stephanie Plancich, PhD and Svetlana Starykh, *Recent Trends in Securities Class Action Litigation: 2009 Year-End Update*, NERA Economic Consulting, at 2 (Dec. 2009).[5] Only a handful of securities class actions ever go to trial, and the average settlement value of securities class actions reached a high of $42 million in 2009, over five

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[5] This report is available at http://www.securitieslitigationtrends.com/Recent_Trends_Report_01.10.pdf.

times the average settlement value of such cases in 1996 and just under twice the average settlement value in 2002. *See id.* at 14.

This case provides an opportunity for the Court to confirm that materiality – like any other circumstance of a federal securities fraud claim – must be pled with particularity. Moreover, if plaintiffs fail to adequately explain how the allegedly false facts were material, or if the allegedly false facts themselves are immaterial as a matter of law, the claim must be dismissed. To the extent that the Ninth Circuit's decision would permit district courts to duck their responsibility to determine at an early stage in a securities fraud case whether a *real* issue of materiality exists for a trier of fact to decide, this Court should reject that approach.

CONCLUSION

For the reasons stated above, *Amici* respectfully urge the Court to reverse the Ninth Circuit's decision. The Court should hold that materiality is subject to the heightened pleading requirements of Rule 9(b) of the Federal Rules of Civil Procedure and is appropriately addressed through a motion to dismiss. The Court also should clarify that its decisions in *TSC Industries* and *Basic* do not foreclose the use of materiality standards to determine whether a plaintiff has sufficiently pled materiality as a matter of law.

Respectfully submitted,

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AMICUS CURIAE BRIEF

No. 09-1156

IN THE

Supreme Court of the United States

MATRIXX INITIATIVES, INC., ET AL.,
Petitioners,

v.

JAMES SIRACUSANO AND NECA-IBEW PENSION FUND,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

BRIEF OF *AMICI CURIAE* STATISTICS EXPERTS PROFESSORS DEIRDRE N. McCLOSKEY AND STEPHEN T. ZILIAK IN SUPPORT OF RESPONDENTS

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INTEREST OF *AMICI CURIAE*[1]

Amici are professors and academics who teach and write on economics, statistics, and the history, philosophy, and rhetoric of economics and statistics as used in business, medicine, and other statistical sciences. *Amici* wish to ensure that the Court properly distinguished 'practical' from mere 'statistical' significance in the context of hypothesis testing when deciding *Matrixx Initiatives, Inc., et al. v. James Siracusano and NECA-IBEW Pension Fund*. *Amici* have no stake in the outcome of this case. They are filing this brief solely as individuals and not on behalf of the institutions with which they are affiliated.

Deirdre N. McCloskey is the Distinguished Professor of Economics, History, English, and Communication at the University of Illinois at Chicago. Previously, she was Visiting Tinbergen Professor (2002-2006) of Philosophy, Economics, and Art and Cultural Studies at Erasmus University of Rotterdam. Since earning her Ph.D. in economics from Harvard University, she has written fourteen books and edited seven more, and has published some three hundred and sixty articles on economic theory, economic history, philosophy, rhetoric, feminism, ethics, and law. Her latest books are *How to be Human – Though an Economist* (Univer-

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[1] Pursuant to Supreme Court Rule 37.6, counsel for *amici* represent that no counsel for a party authored this brief in whole or in part and that none of the parties or their counsel, nor any other person or entity other than *amici*, their members, or their counsel, made a monetary contribution intended to fund the preparation or submission of this brief. Counsel for *amici* also represent that all parties have consented to the filing of this brief, and letters reflecting their blanket consent to the filing of *amicus* briefs have been filed with the Clerk.

sity of Michigan Press 2001), *Measurement and Meaning in Economics* (Stephen T. Ziliak, ed., Edward Elgar 2001), *The Secret Sins of Economics* (Prickly Paradigm Pamphlets, University of Chicago Press, 2002), *The Cult of Statistical Significance: How the Standard Error Costs Us Jobs, Justice, and Lives* [with Stephen Ziliak; University of Michigan Press, 2008], and *The Bourgeois Virtues: Ethics for an Age of Capitalism* (University of Chicago Press, 2006). Before *The Bourgeois Virtues* her best-known books were *The Rhetoric of Economics* (University of Wisconsin Press 2d ed. 1998) and *Crossing: A Memoir* (University of Chicago Press 1999), which was a *New York Times* Notable Book.

Stephen T. Ziliak is Faculty Trustee and Professor of Economics at Roosevelt University. He has held academic appointments at the University of Iowa, Bowling Green State University, Emory University, and the Georgia Institute of Technology. Professor Ziliak's areas of expertise include the study of welfare and poverty; economic history, rhetoric, and philosophy; and history and philosophy of science and statistics. He has written extensively on economic and statistical methods, having published more than three dozen articles, book chapters, and books on the origin, development, and real-world use of statistical significance and hypothesis testing. Professor Ziliak has published articles in *Journal of Economic Literature, Journal of Economic Perspectives, Journal of Economic Methodology, Journal of Socio-Economics, Journal of Economic History, Lancet, Biological Theory, Proceedings of the Joint Statistical Meetings, Quarterly Review of Economics and Finance*, and *Review of Social Economy*. He authored *The Cult of Statistical Significance: How the*

Standard Error Costs Us Jobs, Justice, and Lives (with Deirdre McCloskey, University of Michigan Press, 2008) and he is Associate Editor of *Historical Statistics of the United States: Colonial Times to the Present* (Cambridge University Press, 2006). Professor Ziliak earned his Ph.D. in economics and his Ph.D. Certificate in the rhetoric of the human sciences at the University of Iowa.

INTRODUCTION

Matrixx Initiatives, Inc. is a drug manufacturer that produces Zicam cold remedies. Respondents (Plaintiffs below) have alleged that Matrixx and several of its executives (Petitioners) violated federal securities laws by failing to disclose adverse events linking certain Zicam products with anosmia (the loss of the sense of smell), and issuing misleading statements about Zicam products. The District Court dismissed Respondents' complaint finding that the number of adverse events of which Respondents were aware was not statistically significant. The District Court reasoned that because the adverse events Petitioners withheld from public disclosure could not meet a standard of statistical significance, Respondents failed to allege the element of materiality.

This decision was overturned by the Ninth Circuit Court of Appeals, which found that the District Court erred in applying a strict, bright-line standard of statistical significance to determine materiality. In particular, the Court of Appeals found that a determination of materiality should instead be left to the trier of fact.

In its Supreme Court brief, Petitioners have argued that a standard of statistical significance should be applied when weighing the materiality

of undisclosed adverse events in Section 10(b) cases. Petitioners argue that a statistical significance standard is a commonly used method to determine whether an observed effect is due to chance or real association—be it cause or correlation.[2] Moreover, Petitioners claim that a standard of statistical significance ought to define whether undisclosed information is material to the financial marketplace in securities litigation.[3] As academic and practicing statisticians, we respectfully disagree.

SUMMARY OF ARGUMENT

Statistical significance testing is more complex than simply calculating numbers and determining whether a 5 percent standard has been met. For example, when performing a test of statistical significance, a researcher must weigh the costs of accepting hypotheses that are false against the costs of rejecting hypotheses that are true. To reduce the chance of the latter error (a "Type I" error), researchers can lower their standards of statistical significance, but this would result in an increase in the former type of error (a "Type II" error). The balance must be made by the investigating party in each case.

Problems in significance testing have also been compounded by researchers who prefer to analyze only statistical significance at the expense of practical importance. If an effect is particularly important in practical economic and/or other human terms then the damage from failing to uncover the significance that exists in truth is

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[2] Br. for Pet'r at 34, *Matrixx Initiatives, Inc. v. Siracusano* (No. 09-1156).

[3] *Id.* at 42-44.

particularly grave. As a result, a researcher must strike the correct balance between statistical significance and practical importance. Consequently, a bright-line test of statistical significance would fail to capture important nuances of applied significance testing.

That Petitioners want to place the responsibility of balancing statistical significance and practical importance in the hands of drug manufacturers themselves is troubling. When faced with a particularly important set of undisclosed adverse events, a drug manufacturer may have incentive to avoid disclosing these events until it has received data sufficient to meet a particular standard. In a nutshell, an ethical dilemma exists when the entity conducting the significance test has a vested interest in the outcome of the test.

Finally, it bears mention that significance testing may be particularly cumbersome in the case of adverse events. Because adverse events may gradually trickle in over time, and because it may be implausible to determine the number of individuals actively taking a medication within a given time period, hypothesis tests can be subject to error. Indeed, this is why clinical tests are generally preferred when one is attempting to determine whether certain adverse events are indeed drug-related. As such, a bright-line standard of statistical significance makes little practical sense when determining whether undisclosed adverse events are material.

ARGUMENT

I. A CLARIFICATION OF HYPOTHESIS TESTING AND OF THE CONCEPT OF STATISTICAL SIGNIFICANCE IS WARRANTED IN THIS MATTER

To better understand why the Ninth Circuit's opinion should be affirmed, a basic understanding of hypothesis testing is necessary. Below, we explain what a hypothesis test is, the way the results can be interpreted after such a test is performed, and the two types of errors that a researcher can make when performing a hypothesis test.

A. A Hypothesis Test Seeks to Determine Whether Underlying Data Are Consistent with a Null Hypothesis

Hypothesis testing is one of the most important, if not the most important, concepts in statistical analysis. At a high level, a hypothesis test is performed when a researcher seeks to determine whether data exhibit certain properties or accord with a specific statistical distribution. For example, suppose that a researcher had data on fuel efficiency of a specific model automobile driven at constant speed when outfitted with two different tires. The researcher could use hypothesis testing to determine the level of confidence under which one could conclude that one tire results in improved fuel efficiency.

To provide further detail behind the process, a hypothesis test is first performed by posing a null hypothesis, which is the hypothesis that the statistician wishes to test (for example, the null hypothesis that there is "nil" difference between the two front tires of a motor vehicle in terms of

contributions to fuel efficiency). A test statistic is then calculated, assuming that the "null" hypothesis is true. The testing procedure then involves the determination of whether the test statistic falls into one of two subsets of values: a region under which the null hypothesis is rejected (meaning the tires may actually result in different levels of fuel efficiency) and one under which the null hypothesis cannot be rejected (that is, there is insufficient evidence currently to conclude at some level of significance that the two tires result in different levels of fuel efficiency).

The stylized example above may lend one to believe that hypothesis testing is a simple dichotomous procedure of either rejecting or failing to reject a hypothesis. This is not the case. As we explain below, there are various nuances of hypothesis testing that must be considered. A failure to reject a null hypothesis does not mean that one then accepts it as the truth. Because the harm from erring toward either falsely accepting or falsely rejecting a null hypothesis could be significant, these errors must be balanced accordingly.

B. Failing To Reject the Null Hypothesis Does Not Indicate that the Effect of Interest Is Meaningless or Unimportant

Confusion often surrounds the correct interpretation of the data after a significance test is performed. A rejection of the null hypothesis does not necessarily mean that one accepts the alternate hypothesis.[4] Similarly, failing to reject the null hypothesis does not mean that one should

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[4] *See, e.g.*, David R. Anderson, Dennis J. Sweeney, & Thomas A. Williams, Modern Business Statistics 351 (3d ed. 2006).

then accept it.[5] In particular, if one estimates the size of an effect by calculating a statistical parameter but is unable to reject the null hypothesis that this parameter is equal to zero, one does not then accept the null hypothesis and apply a value of zero to this parameter. Instead the best estimate of the size of the effect is the value of the parameter that one has calculated.[6]

To further illustrate this point, consider the following example. In economics research of some national importance, one estimates a simple consumption function which presumes that consumer spending in the economy is a function of national income, measured by gross domestic product (GDP). Upon estimation, the so-called marginal propensity to consume is derived from the estimated parameter on the *GDP* variable. Suppose that one estimates that the marginal propensity to consume is 0.7—that is, a one dollar increase in GDP then results in a 70 cent increase in consumer spending. Further suppose, however, that this parameter has a *p*-value less than 0.05, which means that it is "statistically insignificant at 5 percent." On the basis of this test, one should not then assume that the marginal propensity to consume is zero. Indeed, one's best estimate of the marginal propensity to consume is still 0.7. Put simply, if an empirical model is correctly specified, the best estimate of an effect is the one derived from that model, regardless of

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[5] *Id.*

[6] Steven Goodman, *A Dirty Dozen: Twelve P-Value Misconceptions*, 45 Seminars in Hematology 135, 136 (2008) (stating that "[t]he effect best supported by the data from a given experiment is always the observed effect, regardless of its significance").

whether a particular level of statistical significance is achieved.

C. There Are Two Types of Errors in Hypothesis Testing: Type I and Type II

Errors are of potential concern when a hypothesis test is performed, and two types of errors can stem from such a test. Type I error occurs when one rejects the null hypothesis when the null hypothesis is true. Type II occurs when one does not reject the null hypothesis when it is false. The chart below helps to clarify this concept.

		Experimental Outcome	
		Reject null hypothesis	*Do not reject null hypothesis*
Truth	*Null hypothesis is false*	Correct Decision	Type II Error
	Null hypothesis is true	Type I Error	Correct Decision

As the table above illustrates,[7] Type I error occurs when the researcher rejects the null hypothesis accidentally. Alternatively, Type II error occurs when the researcher is unable to reject the null hypothesis, when in fact she should.

The importance of Type I error to this matter is that when one identifies the level of significance in a hypothesis test, one has also identified the probability of making a Type I error. For example, suppose that one is testing whether a particular medication lowers cholesterol relative to a place-

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[7] Tables similar to this are commonly presented in statistics texts. *See, e.g.*, Richard J. Larsen & Morris L. Marx, An Introduction to Mathematical Statistics and its Applications, at 299 (2d ed. 1986).

bo. In this test, one could construct the following null and alternate hypotheses.

Null hypothesis: Experimental medication has effect on subject cholesterol equivalent to that of a placebo.

Alternate hypothesis: Effect on subjects' cholesterol from experimental medication is different than the effect from a placebo.

Were one to perform this test at, for example, a 5 percent level of significance, the probability of *incorrectly* rejecting the null hypothesis that the medication has an effect similar to a placebo would therefore be 5 percent.

A Type I error, however, is not the only "bad" outcome when performing the above test. From a testing perspective, another poor outcome would be to fail to reject the null hypothesis when in fact the experimental medication works. This is Type II error.

When analyzing the probability of a Type II error, statisticians will sometimes refer to the "power" of the statistical test, which is the probability of correctly rejecting the null hypothesis. Put differently, a test with high power (where more power is good) is one with a low probability of Type II error (where high Type II error is bad). As we explain below, a cost of decreasing Type I error is that Type II error will increase. Therefore, balance must be struck between these two types of error.

D. The Balance of Type I and Type II Error Informs the Test One Performs and the Significance Level One Chooses

The issue of Type II error brings into focus two important considerations when performing a hypothesis test. *First,* when one has the ability to select from among multiple statistical tests that could all be used to verify a given null hypothesis, it is best to choose the test with greatest power.[8] *Second,* the natural sacrifice of a reduction in Type I error is an increase in Type II error.[9] Because hypothesis testing involves a balance of two different types of error, the actual application of a test of significance is an important aspect of the test itself.

To see this more clearly, consider the example of the experimental medication above. Suppose that in conducting the hypothesis test, the researcher is overly focused on minimizing Type I error. That is, the researcher is overly concerned about finding a statistical effect when one, in truth, does not exist. Exercising great caution when rejecting the hypothesis that the experimental medication has no effect might seem like a good thing. The cost, however, is that it increases the chance of concluding the medication *does not work* when it is indeed effective. This is also a bad outcome and could result in scrapping perfectly effective medicine. Consequently a balance must be struck between these errors, and a singular focus on statistical significance can indeed be inappropriate.

This is discussed in more detail in Section II below.

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[8] *See, e.g., id.* at 303.

[9] *Id.* at 300-03.

II. STATISTICAL SIGNIFICANCE SHOULD BE WEIGHED AGAINST PRACTICAL IMPORTANCE

The concept of practical importance relates to either the magnitude of the effect being studied or the social significance of the effect itself. When a particular result or effect has a high level of practical importance, the cost of Type II error is magnified. As a result, significance testing must be conducted with particular care to avoid eschewing important results simply because they do not meet a particular level of statistical significance.

A. Practical Importance Exists when the Magnitude or Consequence of the Effect Being Studied Is Meaningfully Large

A variable or an effect has practical importance when the size of that effect is meaningfully large.[10] How the balance is struck, the determination made, is a matter of scientific, ethical, and political deliberation which needs to happen prior to the experiment and throughout the research and evaluation process, finally becoming the main determinant of judgments of the goodness or badness of the resultant product—as in the tire and fuel efficiency example. Researchers have noted, however, that too much emphasis has been placed solely on statistical significance at the expense of practical importance.[11] The balance

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[10] Donald N. McCloskey, *The Insignificance of Statistical Significance*, Sci. Am., Apr. 1995, at 32-33.

[11] *Id*; Deirdre N. McCloskey & Stephen T. Ziliak, *The Standard Error of Regressions*, 34 J. Econ. Lit. 97, 109-11 (1996); Deirdre N. McCloskey & Stephen T. Ziliak, *The Unreasonable Ineffectiveness of Fisherian "Tests" in Biology, and Especially in Medicine*, 4 Biological Theory

puts no weight on the practical importance of the outcome. That is, researchers can become too focused on simply rejecting or failing to reject (in a statistical sense) a particular hypothesis rather than also analyzing whether the importance of the effect in question is itself large. As such, too much emphasis could be placed on results found to be statistically significant that have little practical importance, and results or phenomena that are of large practical importance could be ignored or rejected simply because they do not meet a particular criterion of statistical significance.

Because of the trade-off that may need to occur between statistical significance and practical importance, a bright-line rule of statistical significance would be poor practice. That is, it would be impossible to construct an across-the-board rule that could take into account the case-by-case balancing between practical importance and statistical significance that may be desired. Moreover, as we explain in more detail below, one would only worsen this problem by placing the responsibility of conducting such a test in the hands of companies that have a vested interest in certain test outcomes.

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44 (2009) (summarizing instances in applied statistical analysis of medicine in which practical or clinical importance inappropriately lost to statistical significance); Roger E. Kirk, *Practical Significance: A Concept Whose Time Has Come*, 56 Educ. & Psychol. Measurement 746, 746-59 (1996); Steven Goodman, *A Dirty Dozen: Twelve P-Value Misconceptions*, 45 Seminars in Hematology 135, 136-37 (2008) (stating that statistical significance and clinical importance are not synonymous).

B. The Potential Harm from Type II Error Is Large When Practical Importance Is High

As stated above, the problem of using a significance level that is too low is that one is more likely to fail to reject the null hypothesis when it would be appropriate to do so. (In the earlier example of an experimental cholesterol medication, this amounts to concluding the medication does not work when in fact it does.) This problem is magnified when the effect that is being studied is of great practical importance. That is, if a phenomenon in question would, if true, result in great social or economic impact, then the potential harm from disregarding it on the basis of a hypothesis test is heightened.

This particular issue has been identified with regard to statistical analysis of medical data. For example, because clinical trials are often performed with small samples, it may be particularly difficult to garner statistical significance at the five-percent level.[12] Moreover, an ethical problem exists in selecting a significance level that is too low when studying a clinical trial that involves elements of great practical importance.[13] Therefore, care must be taken in applying a significance test to medical data, as an appropriate balance must be struck between Type I and Type II error.

A particular example that is relevant to this discussion is the analysis of adverse events relating to Rofecoxib (brand name Vioxx). An initial analy-

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[12] *See, e.g.*, Douglas G. Altman, Statistics and Ethics in Medical Research III: How Large a Sample?, 281 Brit. Med. J. 1336, 1336-37 (1980); G.T. Lewith & D. Machin, Change the Rules for Clinical Trials in General Practice, J. Royal C. Gen. Prac. 239 (Apr. 1984).

[13] *Id.*

sis of the effectiveness of Vioxx, an anti-inflammatory medication, found that individuals in the Vioxx group suffered from an increased rate of adverse heart-related events (such as infarction and stroke) relative to the control.[14] This increased rate of adverse events, however, was not deemed statistically significant.[15] Therefore, the risk of Vioxx toward heart-related adverse events was downplayed when the drug was first introduced to the market. Once it became evident that heart-related risks did indeed exist, Vioxx was withdrawn from the market.[16] The two-pronged effect of this was that (1) individuals took the drug without fully understanding the potential heart-related risks, and (2) the drug, which could be used by some at acceptable risk[17] was no longer available. Both of these problems could have been avoided had less attention been paid to p-values.

C. The Origins of Significance Testing Further Reveal the Harm of Disregarding Practical Importance

As a corollary to the research on statistical significance versus practical importance, applied statisticians have begun to reexamine the origins of significance testing. The findings of this analysis have revealed that the most commonly held

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[14] Jeffrey R. Lisse et al., *Gastrointestinal Tolerability and Effectiveness of Rofecoxib versus Naproxen in the Treatment of Osteoarthritis*, 139 Annals Internal Med. 539, 543-44 (2003).

[15] *Id.* (discussing that the incidence of heart attacks in the Rofecoxib group was significant at 20 percent).

[16] *Merck Withdraws Vioxx; FDA Issues Public Health Advisory*, FDA Consumer, Nov.-Dec. 2004, at 38.

[17] Ricardo Alonso-Zaldivar, *FDA Gives Painkillers a Pass*, Newsday, Feb. 19, 2005, at A03.

benchmark of statistical significance—that is, five percent—came into prominence because it was an initial suggestion of preference of Ronald Fisher, one of the fathers of the hypothesis test.[18] In particular, Fisher preferred a five-percent rule because at a critical value of 1.96—that is, the critical value for a normally distributed test statistic using the five-percent rule—one would reject the null hypothesis were one's result more than 1.96 standard deviations from the mean. Put differently, Fisher's own preference was to categorize results as significant when they were more than two standard deviations from expectation under the null hypothesis.[19]

Although applied statisticians commonly use the five-percent level when performing significance tests, the fact that this standard exists because an early developer of the test deemed it appropriate highlights an underlying problem of blindly applying this standard in all contexts. Indeed, a group of epidemiologists expressed a similar opinion in a brief submitted to the Supreme Court in *Daubert v. Merrell Dow Pharmaceuticals*.[20] There, several professors in support of petitioners expressed their displeasure with the use of statistical significance testing as the only acceptable method of showing scientific validity in the field of epidemiology.[21] Moreover, these professors noted

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[18] Lisse et al., *supra* note 14, at 543-44.

[19] *Id.*

[20] *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993).

[21] Br. Amici Curiae of Professors Kenneth Rothman, Noel Weiss, James Robins, Raymond Neutra and Steven Stellman, in Supp. of Pet'rs, *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993) (No. 92-102), 1992 WL 12006438, at *5.

that significance testing is often mistaken as a fundamental input of scientific analysis.[22]

D. If the Balance between Type I and Type II Error Should be Left to the Researcher, a Statistical Significance Standard Would Create a Conflict of Interest

The balance between Type I and Type II error is typically determined by the researcher that is conducting the test in question.[23] Therefore, a statistical significance standard in Section 10(b) cases, such as the one sought by Petitioners in this matter,[24] would potentially create a conflict of interest. In particular, the party that may be in the best position to analyze the statistical significance and practical importance of adverse event reports ("AERs") is the drug manufacturer itself, because the manufacturer has data on AERs that have been reported to it by consumers, physicians, and pharmacists. However, the drug manufacturer's incentives are not necessarily aligned with those of either its customers or its investors.

Petitioners in this matter state that a significance standard of five-percent is a general standard and that the Supreme Court has used this standard in the past.[25] However, applied toward the reporting of AERs, such a standard would place an incredible amount of discretionary power in the hands of a party that has particular incentive *not to reject the null hypothesis of the test.* For example, the drug manufacturer might ignore

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[22] *Id.* at 3.

[23] *See, e.g.*, David R. Anderson, Dennis J. Sweeney, & Thomas A. Williams, *Modern Business Statistics* 351 (3d ed. 2006).

[24] Br. for Pet'r at 33, *Matrixx Initiatives, Inc., v. Siracusano* (No 09-1156).

[25] *Id.* at 35.

AERs that, currently, test at p-values of, say, eight or nine percent by deciding that a five percent significance rule is appropriate.

To further see that *any* bright-line standard of statistical significance would be problematic, consider the following. The 5 percent significance rule insists on 19 to 1 odds that the measured effect is real.[26] There is, however, a practical need to keep wide latitude in the odds of uncovering a real effect, which would therefore eschew any bright-line standard of significance. Suppose that a p-value for a particular test comes in at 9 percent. Should this p-value be considered "insignificant" in practical, human, or economic terms? We respectfully answer, "No." For a p-value of .09, the odds of observing the AER is 91 percent divided by 9 percent. Put differently, there are 10-to-1 odds that the adverse effect is "real" (or about a 1 in 10 chance that it is not). Odds of 10-to-1 certainly deserve the attention of responsible parties if the effect in question is a terrible event. Sometimes odds as low as, say, 1.5-to-1 might be relevant.[27] For example, in the case of the Space Shuttle Challenger disaster, the odds were thought to be extremely low that its O-rings would fail. Moreover, the Vioxx matter discussed above provides an additional example. There, the p-value in question was roughly 0.2,[28] which

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[26] At a 5 percent p-value, the probability that the measured effect is "real" is 95 percent, whereas the probability that it is false is 5 percent. Therefore, 95 / 5 equals 19, meaning that the odds of finding a "real" effect are 19 to 1.

[27] Odds of 1.5 to 1 correspond to a p-value of 0.4. That is, the odds of the measured effect being real would be 0.6 / 0.4, or 1.5 to 1.

[28] Lisse et al., *supra* note 14, at 543-44.

equates to odds of 4 to 1 that the measured effect—that is, that Vioxx resulted in increased risk of heart-related adverse events—was real. The study in question rejected these odds as insignificant, a decision that was proven to be incorrect.

One might also consider an example in which a bright-line standard provides a specific benchmark of significance—say, 5 percent. As more AERs gradually become evident, a company may watch a p-value for the significance of the rate of adverse events fall from, say, 10 percent to 8 percent and then to 7 percent. The company might predict that with sufficient time, the 5 percent standard will indeed be met. However, until that standard is met, the result is not significant and no action is needed. Consequently, a bright-line standard of statistical significance in this setting could create a conflict of interest in that a drug manufacturer might have incentive to respond differently to tests of significance than would an impartial researcher.

III. A STATISTICAL SIGNIFICANCE STANDARD WOULD REJECT VALID ADVERSE EVENTS

Problems particular to the analysis of adverse events and to adverse event reporting render significance testing in the area difficult if not unreliable. For example, practitioners in the field of medical research have noted that the problem of sample size can be particularly acute. That is, if a drug does indeed cause an adverse event with greater frequency than a placebo, a very large sample size may be required to detect this difference statistically.[29] Medical data, in particular,

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[29] Altman, *supra* note 12, at 1336-37.

tends to be characterized by small sample sizes.[30] Moreover, even analyses with relatively large sample sizes have been known to fail to uncover true adverse effects in experimental drugs at a five-percent level of significance.[31]

This said, the issue of sample size in uncovering adverse effects still exists. As a result, recommended industry standards are that adverse events should be pursued diligently whether they are significant or insignificant in a statistical sense.[32] In addition, the FDA does not require a statistically significant association between a drug and a given effect to warrant a label change such as a precaution or warning.[33] The sample size problem described above could be compounded by practical problems that exist in adverse event reporting. To see this, first consider the manner

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30 *Id.*

31 *See, e.g.*, Ste phen T. Ziliak, *The Art of Medicine: The Validus Medicus and a New Gold Standard*, 376 The Lancet 324, 325 (2010) (discussing the study of Vioxx); Lisse et al., *supra* note 14, at 543-44 (discussing that the 5 heart attacks of the Rofecoxib group was statistically different from the one heart attack in the control group at only a 20 percent level of significance). There were more than 5,000 individuals in this particular Vioxx study. *Id.*

32 *See* FDA, Center for Drug Evaluation and Research, Guidance for Industry: Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessments (Mar. 2005), at 4 (stating that "[i]t is possible that even a single well-documented case report can be viewed as a signal, particularly if the report describes a positive rechallenge or if the event is extremely rare in the absence of drug use.").

33 *See* 21 C.F.R. § 201.57(e) ("The labeling shall be revised to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug; a causal relationship need not have been proved.").

in which adverse effects could be unearthed in a clinical trial. In a clinical experiment, which is often preferred when performing statistical analysis in epidemiology, test and control groups are well defined and carefully monitored. This makes statistical testing more straightforward, and potentially more powerful relative to an analysis of data obtained from the field.[34]

Because not all adverse events are reported, and because those that are reported may trickle in over time, a *statistical* study of AERs using field data is pre-disposed to understate the true incidence of adverse events. In addition, assessing the number of persons taking the medication within a specific period of time may also be difficult. Consequently, performing a statistical significance test on AER data, particularly before a large amount of that data has been compiled, may be an exercise in futility. That is, with downward bias in the incidence of adverse events, and with a potentially inaccurate measure of the number of users of the drug, a significance test is unlikely to render accurate results.

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[34] *See* Linda Baily, Leon Gordis, & Michael Green, Reference Guide on Epidemiology, *in* Federal Judicial Center, Reference Manual on Scientific Evidence 343 (2d ed. 2000).

CONCLUSION

The judgment of the Ninth Circuit should be affirmed.

Respectfully submitted,

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AMICUS CURIAE BRIEF

Supreme Court, U.S.
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No. 09-1156

IN THE

Supreme Court of the United States

MATRIXX INITIATIVES, *et al.*,
Petitioners,

v.

JAMES SIRACUSANO and NECA-IBEW PENSION FUND,
Respondents.

On Writ of Certiorari to the U.S. Court of Appeals for the Ninth Circuit

BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

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QUESTION PRESENTED

Respondents filed suit under § 10(b) of the Securities Exchange Act of 1934 and Securities and Exchange Commission Rule 10b-5, alleging that petitioners committed securities fraud by failing to disclose "adverse event" reports – *i.e.*, reports by users of a drug that they experienced an adverse even after using the drug. The question presented is:

Whether a plaintiff can state a claim under § 10(b) of the Securities Exchange Act and SEC Rule 10b-5 based on a pharmaceutical company's nondisclosure of adverse event reports even though the reports are not alleged to be statistically significant.

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INTERESTS OF *AMICI CURIAE*

The Washington Legal Foundation (WLF) is a public interest law and policy center with supporters in all 50 States.[1] WLF devotes a substantial portion of its resources to defending free-enterprise, individual rights, and a limited and accountable government.

To that end, WLF has appeared before this and other federal courts in numerous cases related to the proper scope of the federal securities laws. *See, e.g.*, *Morrison v. Nat'l Australia Bank Ltd.*, 130 S. Ct. 2869 (2010); *Stoneridge Inv. Partners, LLC v. Scientific Atlanta, Inc.*, 552 U.S. 148 (2008); *Tellabs, Inc. v. Makor Issue & Rights, Ltd.*, 551 U.S. 308 (2007).

As this Court has recognized, private securities fraud actions, "if not adequately contained, can be employed abusively to impose substantial costs on companies and individuals whose conduct conforms to the law." *Tellabs*, 551 U.S. at 313. "As a check against abusive litigation by private parties," *id.*, Congress adopted the Private Securities Litigation Reform Act of 1995 (PSLRA), 109 Stat. 737, which among other things imposed exacting pleading requirements upon "any private action" arising from the Securities Exchange Act. *See* 15 U.S.C. § 78u-4(b). They included a requirement that the plaintiff "state with particularity facts giving rise to a strong inference" that the defendant acted with an intent to deceive, manipulate,

---

[1] Pursuant to Supreme Court Rule 37.6, WLF states that no counsel for a party authored this brief in whole or in part; and that no person or entity, other than WLF and its counsel, made a monetary contribution intended to fund the preparation and submission of this brief. All parties have consented to the filing of this brief; letters of consent have been lodged with the clerk.

or defraud. 15 U.S.C. § 78u-4(b)(2)(A). WLF is concerned that the decision below, if allowed to stand, would effectively nullify the heightened pleading requirement with respect to scienter

WLF is filing this brief to promote the interests of the business community and the public at large. It has no direct interest, financial or otherwise, in the outcome of this lawsuit. Because of its lack of direct interest, WLF believes that it can assist the Court by providing a perspective distinct from that of any party.

WLF's brief focuses exclusively on the scienter issue. Although WLF agrees with Petitioners that the complaint fails to meet the PSLRA's exacting pleading requirements with respect to materiality, WLF does not address that issue.

STATEMENT OF THE CASE

Petitioner Matrix Initiatives, Inc. is a corporation whose shares are publicly traded. Respondents are individuals who purchased Matrixx shares between October 22, 2003 and February 6, 2004. They filed suit against the corporation and several of its officers (collectively, Mattrix), alleging violations of §§ 10(b) and 20(b) of the Securities Exchange Act of 1934, 15 U.S.C. § 78a *et seq.*, and the Securities and Exchange Commission's Rule 10b-5, 17 C.F.R. § 240.10b-5. They allege that Matrixx materially misled investors by failing to alert them that its principal product, an over-the-counter cold medication marketed under the name Zicam Cold Remedy, caused some users to lose their sense of smell (a condition referred to as anosmia), and

that this emerging safety concern was likely to materially affect Matrixx's financial outlook. After reports of a Zicam-anosmia link were broadcast on ABC-TV's *Good Morning America* on February 6, 2004, the value of Matrixx shares dropped significantly.

On December 15, 2005, the district court granted Matrixx's motion to dismiss the complaint for failure to state a claim, with leave to amend. Pet. App. 35a-54a. The court focused solely on two of the required elements of a securities fraud claim: materiality and scienter. It determined that Respondents had inadequately alleged that any misleading omissions were "material" because Respondents "failed to present evidence of a *statistically significant* correlation between the use of Zicam and anosmia." *Id.* at 50a (emphasis added). It also determined that the complaint inadequately alleged scienter: the complaint failed to allege with particularity facts "giving rise to a strong inference that the defendant acted with the required state of mind with respect to each act or omission alleged to violate the securities law." *Id.* (citing 15 U.S.C. § 78u-4(b)(2)). The court noted that "the Complaint fail[ed] to allege any motive or state of mind with relation to the alleged omissions," and that "[t]here [were] no allegations Defendants disbelieved their statements as to the safety of Zicam, Defendants profited, or attempted to profit from public statements." *Id.* at 51a, 52a. Respondents chose not to amend and instead appealed the dismissal.

The Ninth Circuit reversed and remanded. *Id.* at 1a-34a. The court did not challenge the district court's determination that the complaint's factual allegations did not demonstrate a statistically significant relation-

ship between Zicam and anosmia, but it stated that "the district court erred in relying on the statistical significance standard to conclude that [Respondents] failed adequately to allege materiality." *Id.* at 23a. Rather, the district court should have undertaken "the fact-specific inquiry" into materiality that the appeals court understood to have been required by *Basic Inc. v. Levinson*, 485 U.S. 224 (1988). *Id.* at 24a. Citing *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007), the appeals court determined that the complaint included sufficient factual allegations – regarding "whether the information regarding the possible link between Zicam and anosmia was information that a reasonable investor would have considered significant," *id.* – to state a "plausible" claim for relief and to meet the PSLRA's standards for pleading materiality. *Id.* at 26a.

The appeals court also determined that the complaint's scienter allegations met the requirements of 15 U.S.C. § 78u-4(b)(2). *Id.* at 26a-35a. In determining the issue, the court reviewed not only allegations regarding the link between Zicam and anosmia but also statements made by Matrixx during the class period. *Id.* The court held that "[w]ithholding reports of adverse effects of and lawsuits concerning the product responsible for the company's remarkable sales increase is 'an extreme departure from the standards of ordinary care' and 'presents a danger of misleading buyers and sellers.'" *Id.* at 34a (citing *In re Silicon Graphics Inc. Sec. Litig.*, 183 F.3d 970, 976 (9th Cir. 1999)). The court concluded that "the inference that [Matrixx] withheld the information intentionally or with deliberate recklessness is at least as compelling as the inference that Appellees withheld the information innocently."

Id. at 35a. The decision included no discussion, however, regarding what it thought those "innocent[]" explanations might be, and no analysis regarding the comparative strengths of the competing inferences.

SUMMARY OF ARGUMENT

The PSLRA significantly heightened the requirement for pleading scienter in a securities fraud action. The complaint must "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2)(A). *Tellabs* explained that allegations cannot be said to give rise to the requisite "strong inference" unless they demonstrate that the inference that the defendant acted with scienter is "at least as compelling as any opposing inference one could draw from the alleged facts." 551 U.S. at 324. Yet, the Ninth Circuit determined that Respondents met the "strong inference" without engaging in any analysis of competing inferences.

Had it done so, it would have recognized the existence of a far stronger, non-culpable inference: Mattrix decided not to release information regarding anosmia because it considered the information non-material in the absence of evidence suggesting causal link between use of Zicam and anosmia. Moreover, the appeals court largely misconstrued the factual allegations upon which it relied in determining that the complaint raised a strong inference of scienter.

ARGUMENT

I. IN FINDING THAT THE COMPLAINT ADEQUATELY ALLEGED SCIENTER, THE APPEALS COURT FAILED TO APPLY THE PSLRA'S HEIGHTENED PLEADING REQUIREMENTS

In adopting the PSLRA in 1995, Congress imposed significantly heightened pleading requirements in securities fraud actions brought pursuant to § 10(b) and Rule 10b-5.[2] Under the PSLRA, any private securities complaint alleging that the defendant made a false or misleading statement or omission of "material fact" must "specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed." 15 U.S.C. § 78u-4(b)(1). The complaint must also "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2)(A).

Congress enacted the PSLRA "[A]s a check against abusive litigation by private parties." *Tellabs*, 551 U.S. at 313. Congress recognized that "[p]rivate

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[2] Even before adoption of the PSLRA, securities fraud cases had been subject to the heightened pleading requirements of Fed.R.Civ.P. 9(b), which requires, "In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake."

securities fraud actions, . . . if not adequately controlled, can be employed abusively to impose substantial costs on companies and individuals whose conduct conforms to the law." *Id.* *See* H.R. Rep. No. 104-369, at 31 (1995) (Conf. Rep.) (evidence of abuse included "routine filing of lawsuits . . . whenever there is a significant change in an issuer s stock price, without regard to any underlying culpability of [the defendants]," and "abuse of the discovery process to impose costs so burdensome that it is often economical for the victimized [defendants] to settle"). As acknowledged by the Court, "Proponents of the [PSLRA] argued that these abuses resulted in extortionate settlements, chilled any discussion of issuers' future prospects, and deterred qualified individuals from serving on boards of directors." *Merrill Lynch, Pierce, Fenner & Smith Inc. v. Dabit*, 547 U.S. 71, 81 (2006).

The "required state of mind" that must be pleaded in any securities fraud action is that the defendants intended "to deceive, manipulate, or defraud" the purchasers or sellers of the security. *Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 194 (1976). This requirement to plead scienter is inherently more demanding than the pleading requirement with respect to materiality. It is quite plausible that someone who makes a materially false statement or omission did so without any intent to deceive. The Court has explicitly rejected the argument that "facts that tend to show a materially false or misleading omission) are ordinarily sufficient to show scienter as well." *Merck & Co. v. Reynolds*, 130 S. Ct. 1784, 1797 (2010). The Court explained:

> We recognize that certain statements are such that, to show them false is normally to show scienter as well. It is unlikely, for example, that someone would falsely say "I am not married" without being aware of the fact that his statement is false. Where § 10(b) is at issue, however, the relation of factual falsity and state of mind is more context specific. An incorrect prediction about a firms future earnings, by itself, does not automatically tell us whether the speaker deliberately lied or just made an innocent (and therefore nonactionable) error.

Id. at 1797-98. Similarly, when a pharmaceutical company fails to disclose adverse information reports (reports that later are determined to be material to the company's future earnings), the fact of materiality by itself tells us little about whether the company intended to deceive investors. *See City of Philadelphia v. Fleming Cos.*, 264 F.3d 1245, 1260 (3d Cir. 2001) ("[A]llegations that the defendant possessed knowledge of facts that are later determined to have been material, without more, is not sufficient to demonstrate that the defendant intentionally withheld those facts from, or recklessly disregarded the importance of those facts to, a company's shareholders in order to deceive, manipulate, or defraud.").

Petitioners have convincingly demonstrated that the appeals court erred when it ruled that the complaint adequately pleaded materiality. But even if one accepts the materiality ruling, it does not follow that the complaint also adequately pleaded scienter. WLF respectfully submits that the complaint comes nowhere

close to meeting to rigorous scienter pleading standard imposed by 15 U.S.C. § 78u-4(b)(2)(A).

A. As Interpreted by *Tellabs*, § 4(b)(2)(A) Requires Courts to Examine All Plausible Inferences Regarding The Defendant's Mental State

The Court had occasion in *Tellabs* to construe the PSLRA's heightened pleading standards regarding scienter. The Court observed that § 78u-4(b)(2)(A)'s "strong inference" language "unequivocally raised the bar for pleading scienter." *Tellabs*, 551 U.S. at 321. It held that "Congress required plaintiffs to plead with particularity facts that give rise to a 'strong' – *i.e.*, a powerful or cogent – inference" of scienter. *Id.* at 323.

Moreover, the Court explained:

> The strength of an inference cannot be decided in a vacuum. The inquiry is inherently comparative: How likely is it that one conclusion, as compared to others, follows from the underlying facts? To determine whether the plaintiff has alleged facts that give rise to the requisite "strong inference" of scienter, a court must consider plausible, nonculpable explanations for the defendant's conduct, as well as inferences favoring the plaintiff. . . . [T]he inference of scienter must be more then merely "reasonable" or "permissible" – it must be cogent and compelling, thus strong in light of other explanations.

Id. at 323-24. The Court held that a complaint cannot survive a Rule 12(b)(6) motion to dismiss for failure to state a claim unless "a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *Id.* at 324.

While absence of allegations regarding the defendants' motives for intentionally deceiving investors "is not fatal," the Court stated that motive can be a relevant consideration in determining whether the inference of scienter is sufficiently strong. *Id.* at 325. The Court added that "omissions and ambiguities" in the complaint "count against inferring scienter" because the PSLRA imposes on the plaintiff an obligation to plead "with particularity" facts sufficient to give rise to the requisite "strong inference." *Id.* at 326.

B. Contrary to *Tellabs*, the Appeals Court Engaged in No Consideration to Competing Inferences

In determining that the complaint did not satisfy the PSLRA pleading requirements, the district court engaged in the comparative analysis mandated by *Tellabs*. For example, the district court considered the competing inferences that arguably arose from Matrixx's September 2003 decision not to permit Dr. Bruce Jafek to use the Zicam and Mattrix names in connection with a medical presentation, and concluded as follows:

> Plaintiffs argue that Defendants actions in informing Dr. Jafek that the University of

> Colorado did not have permission to use Zicam marks is e vidence of scienter. However, the argument is not well taken. It is just as reasonable to infer, Defendants were appropriately protecting Zicam's good name and marketability. Furthermore, in the letter from an Allied Waste researcher informing Dr. Jafek he did not have permission to use Zicam marks, Mr. Clarot [one of the Petitioners] stated "we are very much interested in learning more about adverse reports included in your presentation and, to the extent you have valid clinical data supporting your conclusions, we would appreciate receiving that immediately."

Pet. App. 51a.

In contrast, the Ninth Circuit engaged in no such comparative analysis of competing inferences regarding scienter. It mentioned the denial of permission to Dr. Jafek as a factual allegation that contributed to the inference of scienter, *id.* at 32a, but it did not discuss whether "innocent" inferences could be drawn from the same factual allegation.

Indeed, the Ninth Circuit utterly failed to engaged in *any* comparative analysis of competing inferences regarding scienter. Instead, it merely recited allegations from the Consolidated Amended Complaint (CAC) that it deemed supportive of an inference of scienter, *id.* at 28a-33a, and then concluded its analysis with the following *ipse dixit*:

> Viewing the CAC as a whole, the inference of

> scienter is "cogent and at least as compelling" as any "plausible nonculpable explanation[ ]" for Appellees' conduct. *Tellabs*, 551 U.S. at 324. Withholding reports of adverse effects of and lawsuits concerning the product responsible for the company's remarkable sales increase is "an extreme departure from the standards of ordinary care" and "presents a danger of misleading buyers and sellers." *Silicon Graphics*, 183 F. 3d at 976. We therefore conclude that the inference that Appellees withheld the information intentionally or with deliberate recklessness is at least as compelling as the inference that Appellees withheld the information innocently.

Pet. App. 33a-34a.

In the absence of any indication that it complied with *Tellabs*'s requirements that it "must consider any plausible, nonculpable explanations for the defendant's conduct" and then consider whether those explanations are more cogent than an inference that Matrixx acted with scienter, the Ninth Circuit did not begin to comply with *Tellabs*'s mandate. Indeed, as noted above, the Ninth Circuit did not even make reference to the nonculpable explanation (accepted by the district court) for Matrixx's response to Dr. Jafek's September 2003 request to use the Matrixx and Zicam names.

Congress adopted the PSLRA to prevent securities fraud cases from proceeding past the pleadings stage in the absence of strong evidence that the defendants intended to deceive investors. That

congressional purpose would come to naught if the PSLRA's heightened scienter pleading requirement could be deemed satisfied without any meaningful effort being made to determine whether opposing inferences are more cogent than the inference of scienter.

II. THE MOST COGENT INFERENCE FROM THE FACTS ALLEGED IS THAT MATRIXX WITHHELD INFORMATION BECAUSE IT DID NOT CONSIDER THE INFORMATION TO BE MATERIAL

At all stages of this litigation, the focus of Respondents' claim has been Mattrix's failure to disclose information regarding an alleged link between Zicam and anosmia. Thus, the district court dismissed the complaint because it determined that the complaint failed to assert factual allegations demonstrating "a statistically significant correlation between the use of Zicam and anosmia so as to make failure to publically disclose complaints and the University of Colorado study a material omission." Pet. App. 50a. Similarly, the appeals court viewed the claim as one alleging a "fail[ure] to disclose material information regarding Zicam." *Id.* at 3a. After citing nine allegations in the complaint that went "to the question of whether the information regarding the possible link between Zicam and anosmia was information that a reasonable investor would have considered significant," *id.* at 24a-25a, the appeals court concluded that the complaint "sufficiently alleged materiality" under the PSLRA pleading standards. *Id.* at 26a. The question on which this Court granted review is, "Whether a plaintiff can state a claim under § 10(b) of the Securities Exchange Act and SEC

Rule 10b-5 based on a pharmaceutical company's nondisclosure of adverse event reports even though the reports are not alleged to be statistically significant."[3] Thus, although the complaint alleges that Mattrix affirmatively made a number of materially false or misleading statements during the class period, the case has proceeded for the past five years on the basis of Matrixx's failure to disclose information about the alleged Zicam-anosmia link, not on the basis of the false statements. Respondents have limited themselves to arguing that the statements in question were false or misleading due solely to Matrixx's failure to include therein information regarding the alleged Zicam-anosmia link.

In the portion of its opinion that addresses scienter, the Ninth Circuit nonetheless includes a lengthy discussion of the allegedly fa lse statements uttered by Mattrix. Pet. App. 28a-34a. That discussion is wholly appropriate when addressing scienter, even though the alleged falsity and materiality of those statements has never been a focus of this lawsuit. As *Tellabs* explained, "The inquiry . . . is whether *all* of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard." 551 U.S. at 322-23. The Ninth Circuit undertook its examination of each of the allegedly false statements – including the February 2 and 6, 2004 Matrixx press releases – in recognition of its obligation

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[3] *See also* Respondents Opp. Br. at 16 ("[T]he Ninth Circuit's decision concerned the materiality of information that petitioners failed to disclose to investors.").

"to conduct a holistic review" of the entire complaint for purposes of determining whether the factual allegations of the complaint were sufficient to satisfy the PSLRA's scienter requirement. Pet. App. 27a.

The conclusion reached by the Ninth Circuit – that the statements made by Matrixx strengthen the inference that Matrixx acted with scienter – is not well taken. In particular, Ninth Circuit has misconstrued a number of those statements.

More importantly, regardless whether some of the complaint's factual allegations support an inference that Mattrix intended to deceive investors, that inference is not nearly as strong as a competing inference: that Mattrix decided not to release information regarding anosmia because it considered the information non-material in the absence of evidence suggesting causal link between use of Zicam and anosmia.

A. Matrixx Had Reason to Believe that Information Regarding Anosmia Was Non-Material in the Absence of Evidence Suggesting Statistical Significance

The case has proceeded in the lower courts on the assumption that the complaint does not allege facts suggesting a statistically significant association between the use of Zicam and the onset of anosmia.[4] The district

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[4] As Petitioners' brief explains, a link between use of a product and a health event is deemed to be "statistically significant" if the probability is less than 5% that any observed association is

court determined that the 12-to-23 anosmia complaints that Matrixx received before the end of the class period (from among the millions of Zicam uses) were not statistically significant, and held that evidence of failure to disclose non-statistically significant adverse events did not meet § 78u-4(b)(1)'s pleading standard for materiality. Pet. App. 50a. The court offered Respondents an opportunity to amend their pleadings in order to allege statistical significance, *id.* at 53a-54a, but they declined the offer. The appeals court did not challenge the district court's finding regarding statistical significance. It held, however, that factual allegations establishing statistical significance are not required by § 78u-4(b)(1). *Id.* at 23a-24a. Rather, the appeals court held, it is sufficient to allege facts "regarding the possible link between Zicam and anosmia" that a "reasonable investor would have considered significant." *Id* at 24a.

Because the Ninth Circuit held that allegations demonstrating statistical significance were not required by the PSLRA, its determination that Respondents adequately stated a cause of action necessarily assumed the possibility that the complaint did not include such allegations. Accordingly, the scienter issue must be addressed based on the assumption that the anosmia reports received by Matrixx during the class period were not statistically significant.[5] Under those circum-

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actually the result of random error. Courts routinely rely on statistical significance to distinguish between random occurrences and associations that could be causal. *See* Pet. Br. 34-42.

[5] Moreover, to the extent that there is any doubt regarding whether the complaint adequately alleges statistical significance,

stances, the most cogent inference to be drawn from the complaint's allegations is that Matrixx decided not to disclose the anosmia reports because it believed in good faith that the securities laws did not require the disclosure of adverse event reports that were not statistically significant.

Pre-2004 federal appellate court decisions were unanimous in concluding that securities fraud plaintiffs suing a pharmaceutical company for failing to disclose adverse event reports could satisfy neither the PSLRA nor the Rule 9(b) pleading standards for materiality and scienter unless they alleged facts demonstrating a statistically significant association between use of the company's drug and the reported condition. *See, e.g., Oran v. Stafford*, 226 F.3d 275, 284 (3d Cir. 2000); *In re: Carter-Wallace, Inc. Securities Litigation*, 220 F.3d 36, 41 (2d Cir. 2000); *In re: Carter-Wallace, Inc. Securities Litigation*, 150 F.3d 153, 157 (2d Cir. 1998) ("Drug companies need not disclose isolated reports of illnesses suffered by users of their drugs until those reports provide statistically significant evidence that the ill effects may be caused by – rather than randomly associated with – use of the drugs and are sufficiently serious and frequent to affect future earnings."). Given the state of the law during the 2003-04 class period, a pharmaceutical company in Matrixx's shoes almost surely would have believed that it was not required to disclose adverse event reports that were not statistically significant. By far the most cogent inference regarding

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the doubt must be resolved in Matrixx's favor. *Tellabs* held that any "omissions and ambiguities" in a complaint "count against inferring scienter." 551 U.S. 326.

Matrixx's state of mind, therefore, is that Matrixx decided not to disclose the adverse event reports because it believed that disclosure was neither required nor appropriate, not because it sought to deceive investors.

The Court's ultimate disposition of the materiality issue will not affect disposition of the scienter issue because it will not affect the inferences that may properly be drawn from Matrixx's decision not to disclose the anosmia complaints received from Zicam users. Thus, even if the Court determines that Respondents' complaint meets the PSLRA's materiality pleading requirement despite the failure to allege statistical significance, that determination would have been unknowable in 2003-04 and thus would shed no light on Matrixx's thought processes at the time.

Moreover, Petitioner has pointed out numerous other reasons why Mattrix had good reason to believe that the 2003-04 anosmia complaints were not statistically significant.[6] In particular, the existence of an adverse event report suggests nothing by itself

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[6] Indeed, although FDA concluded in 2009 that the alleged association between Zicam and anosmia raised legitimate safety concerns, that issue is far from settled. In its most recent 10-K report filed with the SEC, Matrixx asserted, "[W]e disagree strongly with the FDA's allegations that Zicam Cold Remedy nasal gel products may be unsafe. . . . The Company's position is supported by the cumulative science, a multi-disciplinary panel of scientists, and the decisions of 10 separate federal judges in 10 different cases in multiple jurisdictions." Matrixx Initiatives Inc., Form 10-K (Annual Report) (filed June 7, 2010 for the period ending March 31, 2010) at 14.

regarding causation.[7] Zicam users occasionally experience adverse medical conditions, but so do many people who do not use Zicam. Pet. Br. at 46. Matrixx had especially good reason to be wary of claims that Zicam caused anosmia, because (as Respondents concede) the common cold is a leading factor affecting sense of smell and thus "the populat. n most likely to use cold remedy products is already at increased risk of developing anosmia." Complaint ¶38, J.A. 78a. Accordingly, Matrixx would have had little basis for concluding that the small number of reported anosmia cases were being caused by use of Zicam rather than by the medical condition for which the Zicam was being taken.

The Ninth Circuit cited to "existing studies linking zinc sulfate to the loss of smell." Pet. App. 5a. But Zicam has never contained zinc sulfate. Its active ingredient is zinc gluconate, a different compound. Matrixx would have had good reason to doubt the relevance – to the Zicam safety issue – of polio studios from the 1930s regarding the effects of zinc sulfate.

In sum, the allegations of the complaint underscore that Matrixx had good reason to believe that the anosmia reports were not statistically significant and thus not "material." Under those circumstances, the most cogent inference – regardless whether the reports are ultimately deemed "material" – is that

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[7] Moreover, even if there is a true association between two factors, there may be no causal relationship. For example, just because gray hair is associated with death rate does not mean that gray hair causes death.

Matrixx decided not to disclose the reports because it deemed disclosure neither required nor appropriate, not because it wished to deceive investors.

B. Matrixx's November 2003 SEC Filing Does Not Support an Inference of Scienter

On October 14, 2003, the first product liability suit – alleging damage to sense of smell caused by use of Zicam – was filed against Matrixx. On November 12, 2003, Matrixx filed a Form 10-Q with the SEC for the third quarter of 2003. The Form 10-Q made no reference to the October 14 lawsuit. The Ninth Circuit concluded that the omission created an inference of scienter because "[w]ithholding reports of . . . lawsuits concerning the product responsible for the company's remarkable sales increase is an extreme departure from the standards of ordinary care and presents a danger of misleading buyer or sellers." Pet. App. 33a.

The appeals court's finding is without merit. Far from constituting "an extreme departure from the standards of ordinary care," Matrixx's decision not to reference the lawsuit in the 10-Q report fully complied with SEC regulations. The duty to disclose lawsuits in SEC filings is governed by the SEC's Regulation S-K, 17 C.F.R. § 229.103. SEC guidance provides that "[a] legal proceeding need only be reported in the 10-Q filed for the quarter in which it became a reportable event." SEC Release No. 5949, *Amendments to Disclosure Forms and Regulations* (July 28, 1978), 1978 WL 170913, *27. The Matrixx 10-Q at issue covered the quarter ending September 30, 2003, two weeks before

the filing of the first product liability suit. Thus, the lawsuit was not reportable until the next quarterly 10-Q; and that next 10-Q did, in fact, disclose the October 14 lawsuit. Moreover, Regulation S-K provides that pending litigation generally need not be disclosed in a 10-Q unless the claim for damages exceeds 10% of the company's current assets. *See* 17 C.F.R. § 229.103, Instruction 2. Damages sought in the October 14 lawsuit constituted but a minuscule fraction of Matrixx's current assets, far less than 10%. Indeed, Respondents have never alleged that Matrixx violated Regulation S-K by failing to report legal proceedings.

Compliance with Regulation S-K does not absolutely preclude a finding, in subsequent securities fraud litigation, that information about a lawsuit was material and thus should have been disclosed (whether in an SEC filing or elsewhere). *City of Philadelphia v. Fleming Cos.*, 264 F.3d at 1267. Nonetheless, courts generally accept SEC determinations with respect to reporting obligations to be "persuasive authority" regarding materiality determinations. *Id.* at 1266-67. *See also, Basic Inc. v. Levinson,* 485 U.S. 224, 239 n.16 (1988) ("The SEC's insights are helpful, and we accord them due deference."). In light of Mattrix's compliance with SEC disclosure requirements, the appeals court's determination that nondisclosure represented "an extreme departure from the standards of ordinary care" is simply implausible. Nothing about the non-disclosure creates any inference that Matrixx *intended* to deceive investors.

The appeals court stated that the inference of scienter arose in part because the November 12, 2003,

Form 10-Q included boilerplate language regarding the risks of product liability litigation. Pet. App. 30a. The court faulted Matrixx for discussing those risks while giving "no indication that the risk may already have come to fruition." *Id.* The court analogized the situation to *Berson v. Applied Signal Tech., Inc.*, 527 F.3d 982 (9th Cir. 2008), in which a company was faulted for boasting (in one of its SEC filings) that it had a significant amount of backlogged work, without disclosing that some of the backlogged work had actually been stopped and was "at serious risk of being cancelled altogether." *Id.* at 29a-30a. The Ninth Circuit thought that the 10-Q might mislead some investors because, "[s]imilar to *Berson*," it spoke of the risk of product liability claims "in the abstract" without mentioning that one lawsuit had already been filed. *Id.* at 30a. The analogy to *Berson* is wholly inapt, and the criticism of Matrixx makes no sense. The boilerplate language in the Form 10-Q could not possibly have misled investors because it said nothing to suggest that no product liability lawsuits had been filed, and (unlike the SEC filing in *Berson*) it made no boasts that placed Matrixx in a more favorable light. Moreover, there is no plausible basis for inferring that Matrixx included the boilerplate language (while omitting any mention of the October 12 lawsuit) for the purpose of deceiving investors.

C. Matrixx's Decision to Investigate All Complaints Thoroughly Before Deciding How To Proceed Does Not Support an Inference of Scienter

Based largely on Matrixx's failure to disclose

immediately every report it received regarding anosmia, the Ninth Circuit inferred that Matrixx intended to deceive investors regarding its financial prospects. WLF respectfully submits, to the contrary, that Matrixx's course of conduct was much more consistent with that of a pharmaceutical company acting proactively and prudently to discover the nature of the association (if any) between Zicam and anosmia before issuing any statements on the topic.

For example, it was Respondent Timothy Clarot, Matrixx's Vice President for Research and Development, who first reached out to Dr. Miriam Linschoten in September 2002 to learn more about her treatment of a patient suffering from anosmia. Complaint ¶26, J.A. 68a. Clarot was aware of the treatment because the patient had contacted Matrixx directly. *Id.* Far from seeking to suppress Dr. Linschoten's information, Clarot sought information about her patient, stated that Matrixx had hired a consultant to review Zicam, and requested that she send him information about studies that linked zinc *sulfate* to loss of smell. *Id.* at 68a-69a. After he received the information about those studies, he called Linschoten again to request her participation in animal studies that Matrixx planned to conduct regarding the effects of Zicam. Complaint ¶27, J.A. 69a.

The Ninth Circuit faulted Matrixx for denying Dr. Jafek permission to use the names "Matrixx" and "Zicam" in his September 2003 poster presentation to the American Rhinologic Society. Pet. App. 32a. The appeals court concluded that this refusal supported an inference that Matrixx intended to deceive investors. *Id.* But as noted above, the district court rejected that

inference, concluding, "It is just as reasonable to infer, Defendants were appropriately protecting Zicam's good name and marketability." *Id.* at 51a. The appeals court never considered that alternative, nonculpable inference. Nor did Matrixx's actions lead to the suppression of any medical data: Dr. Jafek still alerted other doctors to his suspicions regarding a causal link between zinc gluconate and anosmia, and other doctors who were interested in his findings would have had no difficulty determining which over-the-counter medications contained zinc gluconate.

Moreover, the very letter to Dr. Jafek upon which the Ninth Circuit relied also evidenced Mattrix's eagerness to learn more about any link between Zicam and anosmia. J.A. 117a-119a. The letter stated that Matrixx had conducted two double-blind randomized clinical trials of zinc gluconate, and there were no reports of anosmia in either study. *Id.* The letter nonetheless added:

> [W]e are very much interested in learning more about the adverse reports included in your presentation and, to the extent you have clinical data supporting your conclusions, we would appreciate receiving that immediately.

Id. at 117a-118a.

The complaint contains no allegation that Dr. Jafek supplied the requested information, or that he ever conducted a clinical study regarding the alleged Zicam-anosmia link. Nonetheless, as the complaint concedes, in response to Dr. Jafek's poster presentation

Matrixx convened a two-day meeting of physicians and scientists "to review current information on smell disorders." Complaint ¶ 45, J.A. 82a.

The absence of any personal financial motive for deceiving investors also supports an inference that Matrixx was delaying disclosure for the purpose of investigating the alleged Zicam-anosmia link more fully. The Ninth Circuit conceded that Respondents had not alleged that Matrixx or its executives had "engaged in unusual or suspicious stock sales at the same time that they were attempting to downplay the reports of anosmia," Pet. App. 32a, but then cited *Tellabs* for the proposition that while "motive can be a relevant consideration," the "absence of a motive allegation is not fatal" to a securities fraud claim." *Id.* (quoting *Tellabs*, 551 U.S. at 324). But while the absence of financial motivation may not *preclude* a finding that Matrixx acted with scienter, it was certainly a highly relevant consideration. Accordingly, the Ninth Circuit erred in failing to draw therefrom an inference of nonculpable intent and comparing the cogency of that inference to the inference that Matrixx intended to deceive investors.

Finally, the Ninth Circuit inaccurately stated that the two-day meeting of physicians and scientists was convened in February 2004 in response to the information disclosed in the February 6, 2004 *Good Morning America* broadcast. Pet. App. 33a. In fact, that meeting had been in the works for months and, as conceded in the complaint, was organized in response to Dr. Jafek's September 2003 poster presentation. Complaint ¶ 45, J.A. 82a.

In sum, the most cogent inference regarding Matrixx's state of mind is that it delayed releasing information regarding anosmia complaints in order to provide itself an opportunity to carefully review all evidence regarding any link between Zicam and anosmia. Courts have recognized that a delay-reporting-while-conducting-studies rationale is a prudent course of action and negates an inference that the manufacturer of a drug or medical device intended to deceive investors. *See, e.g., In re Medtronic Inc. Securities Litigation*, 618 F. Supp. 2d 1016, 1036 (D. Minn. 2009).

D. Matrixx's February 2 and 6, 2004 Press Releases Do Not Support an Inference of Scienter

In response to press reports linking Zicam to anosmia, Matrixx issued largely identical press releases on February 2, 2004, and February 6, 2004, denying a causal link between Zicam and anosmia. The Ninth Circuit concluded that the press releases contained materially false information and thus that their issuance strengthened the inference of scienter. Pet. App. 30a, 31, 33a.

The Ninth Circuit's conclusion is based on a mischaracterization of the press releases. The principal paragraph in both press releases read as follows:

> In no clinical trial of intranasal zinc gluconate gel products has there been a single report of lost or diminished olfactory function (sense of smell).

> Rather, the safety and efficacy of zinc gluconate for the treatment of symptoms related to the common cold have been well established in two double-blind, placebo controlled, randomized clinical trails. In fact, in neither study were there any reports of anosmia related to the use of the compound. The overall incidence of adverse events associated with zinc gluconate was extremely low, with no statistically significant difference between the adverse event rates for the treated and placebo subsets.

J.A. 193a-194a, 201a-202a. The complaint contains no allegations suggesting that any of the preceding statements are inaccurate.

The Ninth Circuit faulted the press releases for failing to "say whether Mattrix studied the intranasal use of zinc gluconate for safety, as opposed to efficacy." Pet. App. 31a. That is not a fair criticism of the press releases, which neither stated nor inferred that the two studies were explicitly designed to determine whether there was a causal connection between use of Zicam and anosmia or any other medical condition. Rather, a fair reading of the releases indicates that Mattrix's safety claims were based on: (1) the absence from the clinical trials of "any reports of anosmia related to the use of" zinc gluconate; and (2) the absence of any meaningful difference in "[t]he overall incidence of adverse events" between those treated with Zicam and those treated with a placebo. That evidence was more than sufficient for Matrixx to claim truthfully that the "safety and efficacy of zinc gluconate for the treatment of symptoms related to the common cold have been well established."

The Ninth Circuit also concluded that the inference of scienter was strengthened by alleged inconsistencies between the press releases and a later statement (contained in a February 19, 2004 Form 8-K filing with the SEC) that Matrixx had determined that "there was insufficient evidence to determine whether zinc gluconate affected the sense of smell." Pet. App. 33a. It also stated that "Mattrix allegedly subsequently admitted that 'they don't know if their nasal gel could cause loss of smell.'" *Id.* at 22a n.6 (quoting from a March 4, 2004 news story, which apparently was based on the Form 8-K filing).

The appeals court has mischaracterized the Form 8-K. Matrixx did not state that company management had determined that it did not know "if their nasal gel could cause loss of smell." The press releases accurately stated that all available clinical evidence indicated that Zicam did not cause anosmia. The Form 8-K did not contradict that statement. Rather, it stated that a panel of doctors and scientists convened by Matrixx had determined, in the days following issuance of the press releases, that more evidence was needed because "there was insufficient evidence to determine whether zinc gluconate affected the sense of smell." Matrixx management responded to that determination in a wholly appropriate manner: it filed a Form 8-K with the SEC and initiated a study focusing on whether there existed a causal relationship between use of Zicam and anosmia.

The Ninth Circuit said that the February 2 press release was inaccurate because by that date "a strong

inference can be drawn that [Matrixx] knew that the statements alleging a link between Zicam and anosmia were not 'completely unfounded and misleading.'" Pet. App. 31a. That sentence mischaracterizes the press release. The press release termed "completely unfounded and misleading" claims that Zicam products "cause" anosmia, not (as the Ninth Circuit phrased it) claims alleging "a link" between Zicam and anosmia. J.A. 193a.

Finally, the Ninth Circuit faulted the February 2 press release for labeling as "completely unfounded and misleading" a January 30, 2004 Dow Jones report "that the FDA was investigating Zicam and anosmia." Pet. App. 32a-33a. The appeals court once again mischaracterized the press release. Matrixx did not deny that FDA was investigating Zicam; rather, it stated that it was "not aware of an FDA inquiry." J.A. 193a. Indeed, the complaint itself does not allege that FDA was conducting an investigation in January 2004, and even now there is nothing in the record to indicate that an FDA investigation was taking place.

In sum, the February 2 and 6, 2004 press releases were accurate, and nothing in either document supports the Ninth Circuit's conclusion that issuance of those documents supports an inference of scienter.

CONCLUSION

Amici curiae request that the Court reverse the decision of the court of appeals.

Respectfully submitted,

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